In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS
No. 14-078V
(To be published)

* *		
	*	Special Master Corcoran
CHRISTINA E. POPE, *parent and next friend of*	*	
B.P., *a minor,*	*	Filed: May 1, 2017
	*	
Petitioner,	*	Decision without Hearing;
	*	Dismissal; Diphtheria Tetanus
v.	*	acellular-Pertussis ("DTaP")
	*	Vaccine; Pneumococcal Conjugate
SECRETARY OF HEALTH AND	*	Vaccine ("PCV"); Encephalopathic
HUMAN SERVICES,	*	Developmental Regression; Autism;
	*	Immunoglobulin Deficiency;
Respondent.	*	Mitochondrial Dysfunction.
	*	
* *		

Richard Gage, Richard Gage, P.C., Cheyenne, WY, for Petitioner.

Lynn E. Ricciardella, U.S. Dep't of Justice, Washington, DC, for Respondent.

DECISION GRANTING MOTION TO DISMISS CASE[1]

On January 27, 2014, Christina E. Pope, on behalf of her son, B.P., filed a petition seeking compensation under the National Vaccine Injury Compensation Program ("Vaccine Program").[2] In it, Mrs. Pope alleged that the Diphtheria Tetanus acellular-Pertussis ("DTaP") and pneumococcal conjugate ("PCV") vaccines B.P. received on May 11, 2011, caused him to

[1] This decision will be posted on the United States Court of Federal Claims's website, in accordance with the E-Government Act of 2002, 44 U.S.C. § 3501 (2012). As provided by 42 U.S.C. § 300aa-12(d)(4)(B), however, the parties may object to the published decision's inclusion of certain kinds of confidential information. Specifically, under Vaccine Rule 18(b), each party has fourteen days within which to request redaction "of any information furnished by that party: (1) that is a trade secret or commercial or financial in substance and is privileged or confidential; or (2) that includes medical files or similar files, the disclosure of which would constitute a clearly unwarranted invasion of privacy." Vaccine Rule 18(b). Otherwise, the whole decision will be available to the public. *Id*.

[2] The Vaccine Program comprises Part 2 of the National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3758, codified as amended, 42 U.S.C. §§ 300aa-10 through 34 (2012) [hereinafter "Vaccine Act" or "the Act"]. Individual section references hereafter will be to § 300aa of the Act.

experience an encephalopathic developmental regression into autism, as well as immunoglobulin deficiencies, exacerbated by underlying mitochondrial dysfunction. Petition at 1-2.

After the parties filed expert reports, and based upon my initial review of the case record in light of the disposition of similar cases previously adjudicated in the Vaccine Program, I proposed that the matter be decided without holding an evidentiary hearing, and I invited the parties to brief the substantive merits of Petitioner's claim. To that end, Respondent filed a motion to dismiss, dated August 29, 2016 (ECF No. 46) ("Mot."), to which Petitioner responded on November 14, 2016 (ECF No. 54) ("Opp."). Having completed my review of the evidentiary record and the parties' filings, I hereby **GRANT** Respondent's Motion for a Ruling on the Record Dismissing the Case, and **DENY** Petitioner's request for compensation, for the reasons stated below.

I. FACTUAL BACKGROUND

Early Medical History

B.P. was born via spontaneous vaginal delivery on February 3, 2010, following a normal pregnancy, and he was discharged home two days later. Ex. 1 at 10-11; Ex. 2 at 1-9.[3] During his first year of life, B.P. had well-child and routine pediatric visits at Wilmington Health Clinic ("WHC") in Wilmington, North Carolina, with no noted growth or developmental concerns. *See*, *e.g.,* Ex. 3 at 46-115. He received his initial routine childhood vaccinations on April 6, June 8, and August 16, 2010, respectively, and his first influenza ("flu") vaccine on November 9, 2010. Ex. 9 at 1-2.

As the contemporaneous medical records reveal, B.P.'s health in his first year of life was characterized by the kind of illnesses that many otherwise-healthy infants experience. Thus, B.P. was seen on several occasions for a variety of infections. *See, e.g*., Ex. 3 at 46-48 (2/9/2011, diagnosed with nasopharyngitis/viral infection), 51-52 (12/21/2010, diagnosed with bronchitis, possibly viral), 64-65 (11/9/2010, diagnosed with sinusitis), 75-81 (8/31/2010, 9/1/2010, and 9/8/2010, diagnosed with presumed infectious diarrhea, viral illness, and a canker sore), 86-90 (6/10/2010 and 6/25/2010, diagnosed with viral infection and presumed infectious diarrhea), 106-08 (3/16/2010, diagnosed with viral nasopharyngitis). Starting on March 24, 2010, at approximately seven weeks of age, B.P. was also diagnosed with and treated for chronic otitis media ("OM"). *Id.* at 49-104. B.P. underwent bilateral tympanostomy tube placement in his ears in December 2010 to treat the condition. *Id.* at 49-51, 54-58.

[3] Petitioner's exhibits in this case are referenced numerically, while Respondent's exhibits are referenced alphabetically.

Despite the above, Petitioner contends that the record omits important details about B.P.'s health – particularly his reaction to the vaccines he received prior to those at issue herein. Thus, Mrs. Pope maintains that after each round of the aforementioned vaccinations, B.P. would experience a high fever, arch his back, and cry uncontrollably. *See, e.g.,* Ex. 60 (Affidavit of Christina Pope) at ¶¶ 2-7. Mrs. Pope alleges that her questions about these reactions were not taken seriously, however, nor did treaters even record them. *Id.* at ¶¶ 5-6. Thus, at his four-month well-child check on June 8, 2010, B.P. (in good health at the time) received several additional vaccinations. Ex. 3 at 92, 94. Two days later, on June 10, 2010, B.P. returned to the pediatrician due to a fever and congestion, which was diagnosed as merely a viral reaction (when according to Mrs. Pope, it was evidence of his vaccine sensitivity). *Id.* at 89- 90; Ex. 60 at ¶ 2.

The first half of 2011 mirrored 2010 in terms of B.P.'s health and the treatments he received, with additional immunizations administered at the appropriate times. *See, e.g.,* Ex. 9 at 1-2. B.P. was seen in March and April 2011, much like the prior year, for upper respiratory infections and comparable conditions (*i.e.* a runny nose or congestion) and received treatment for the same. Ex. 3 at 40-45. No developmental concerns were noted for B.P. in this time period. *See, e.g., id.* at 46-48 (records from B.P.'s one-year well-child visit on February 9, 2011).

Receipt of May 2011 Vaccines and Subsequent Medical History

B.P. had his fifteen-month well-child visit on May 11, 2011. Ex. 3 at 37-39. B.P.'s development remained normal, and by this point in his life he could stand alone, stoop and recover, walk well, say two words together, wave "bye-bye," say "Dada [and] Mama - Specific," and mimic activities. *Id.* at 37. At this time, he received his fourth dose of the PCV vaccine and first DTaP vaccine dose. *Id*. at 39; Ex. 9 at 3. Immediately thereafter, Mrs. Pope alleges B.P. again spiked a fever and was very irritable and lethargic for the next several days, although the medical records do not corroborate these contentions. Ex. 60 at ¶¶ 6-8. Petitioner also claims to have reported to the pediatrician that B.P.'s eye contact was intermittent, but she was informed that there were no grounds for worry. *Id.*

The remainder of May and the first half of June passed without medical incident. Then, six weeks after receiving the vaccinations in question, on June 28, 2011, B.P. was taken back to WHC with a two-day history of fussy behavior and touching his ears without a fever. Ex. 3 at 35-36. The record, however, reflects that B.P. was teething, and his physical exam was otherwise normal. *Id*. B.P was seen again at WHC on July 13, 2011, at seventeen months of age, for a six-month follow-up for his tympanostomy tubes. *Id.* at 33-34. His pediatrician noted that B.P. had normal communication for his age and that his tubes remained in place. *Id*. B.P. continued to be seen at WHC throughout his second year of life for upper respiratory and ear infections. *See id*. at 22-31.

Evidence of Developmental Problems and/or Regression

The parties dispute when B.P. first began to display signs of developmental problems or regression. Petitioner argues that manifestations of B.P.'s developmental problems began immediately after the May 2011 vaccinations. Thus, Mrs. Pope maintains that post-vaccination, B.P. could no longer point his index finger, catch and throw a ball, march his feet, or wave his hand for "hi" or "bye-bye." Ex. 60 at ¶ 9. She also alleges that he lost the ability to shake his head "no" or nod his head "yes," could not identify body parts, and experienced deterioration of language skills, including losing words he had previously used, such as "mama" and "dada." *Id.* Mrs. Pope consistently alleges that she informed the pediatrician of her observations of B.P.'s regression, but she was told that it was normal or that it could be harmful to B.P.'s future (especially once in school) to record the possibility that B.P. was experiencing autism or a similar developmental problem in the treatment history. *Id.* at ¶ 10.

By contrast, the contemporaneous record shifts the onset of B.P.'s problems to a much later date – early 2012, eight months after the relevant vaccinations – and reflects no instance until that time in which either Petitioner or a treater noted any concerns about B.P.'s development. Thus, on January 4, 2012, Petitioner took B.P. (now twenty-three months old) to WHC for congestion that had been ongoing for one week, plus a diaper rash that had worsened over the past two days. Ex. 3 at 19-21. At this visit, Mrs. Pope is recorded as stating that her in-laws had expressed concern that B.P. had autism, because he would wave his arms when he was upset and spoke few two-word sentences. *Id*. The pediatrician's notes echo these concerns, noting that B.P.'s speech "may be a bit delayed," but he otherwise determined that B.P.'s behavior was within the "realm of normal" and diagnosed him with OM, a diaper rash, and possible developmental delay. *Id.* at 21. B.P.'s treater requested that B.P. be seen again in one month in order to assess whether additional developmental symptoms warranted further evaluation. *Id.*

B.P. was brought back to his pediatrician's office on January 31, 2012, for a sick visit, where he was diagnosed with bronchiolitis and OM, but there was no further mention of any of the developmental concerns expressed at the January 4th visit. Ex. 3 at 17-18. B.P.'s pediatrician thereafter saw him three more times in February 2012 for bronchiolitis and OM. *Id*. at 9-16. He was also seen for a rash on March 13, 2012. *Id*. at 7-8. The contemporaneous notes from these visits are similarly silent on the matter of additional developmental concerns.

On May 18, 2012, B.P. was evaluated for several episodes of purulent otorrhea[4] and was diagnosed with Eustachian tube dysfunction. Ex. 3 at 4-6. The pediatrician noted that B.P.'s hearing appeared normal, but that Mrs. Pope would be obtaining a speech evaluation for B.P. *Id*.

[4] An otorrhea is a discharge from the ear; purulent otorrhea indicates that the discharge contains pus. *See Dorland's Medical Dictionary* 1351, 1558 (32nd ed. 2012) (hereinafter *Dorland's*).

at 6. The records from this visit include "developmental delay" in B.P.'s medical history, but the examination from this visit (which is limited in description) does not set forth any specific observations of developmental problems in communication or physical acts. *Id.* at 4-6.

Petitioner returned to WHC with B.P. (then twenty-eight months old) "to discuss behavior issues and development" on June 21, 2012. Ex. 3 at 1. She now reported that B.P. was still flapping his hands and would become overstimulated if he saw something that upset him. *Id*. She also stated (for the first time in the contemporaneous records) that B.P.'s speech was delayed – he knew some words and occasionally put two words together, but he mostly babbled and seemed "a little tongue-tied." *Id*. The pediatrician noted that B.P.'s fine and gross motor skills appeared normal, along with his hearing, but that he did display some sensory issues. *Id*. B.P. was accordingly diagnosed with speech delay and possible developmental delay. *Id*. at 3. While the pediatrician did not express the formal view that B.P. was on the autism spectrum, he nevertheless referred him for a developmental evaluation. *Id.*

On July 19, 2012, Petitioner took B.P. to the Wilmington Children's Developmental Services Agency ("CDSA") for an evaluation, and he was diagnosed with autism, delayed milestones, and a language disorder. Ex. 18 at 3-10. As such, he was found eligible for the North Carolina Infant-Toddler Program.[5] *Id.* at 1, 9. The detailed narrative of the CDSA report describes delays in various skills, but it does not appear to mention any regression. *Id*. at 3-10. It also contains no statements regarding when the Popes, or any of B.P.'s other caregivers, first noticed his developmental problems.

Dr. Harum's Treatment of B.P.

On July 31, 2012, B.P. began seeing Karen Harum, M.D., at the Clinic for Special Children, because of his parents' concerns about his autism diagnosis. Ex. 5 at 38-40. B.P.'s parents reported that he had stopped using words and naming body parts "closer to two years [old]," (or around February 2012 – nine months from the vaccinations at issue), although they also asserted that his developmental problems were first evident after the 15-month-old vaccinations at issue herein. *Id*. at 38 (B.P. "suddenly changed" after receiving the vaccinations in May 2011). These records also present the first instance in which developmental regression (as opposed to delay) is mentioned as a concern. *Id.* at 38.[6]

[5] The North Carolina Infant-Toddler Program provides support and services for families and their children who have special needs. *See* North Carolina Infant-Toddler Program, NC Department of Health and Human Services, http://www.beearly nc.gov (last accessed Apr. 19, 2017).

[6] As already noted, Mrs. Pope has alleged (in her witness affidavits, as well as some history recitations made to treaters after this date) that she observed B.P.'s regression prior to this time.

The records from the Popes's first visit with Dr. Harum in July 2012 contain a variety of representations about B.P.'s medical history that are contradicted, or at least not corroborated, by prior contemporaneous medical records.[7] In particular, Petitioner appears to have informed Dr. Harum that B.P. had experienced a low grade fever and a diarrheal illness right after the May 2011 vaccinations, followed by a gradual loss in skills – when the contemporaneous medical records mention no such reaction or symptoms. *See, e.g.,* Ex. 3 at 24-39 (no record of a low grade fever, diarrheal illness, or loss of skills in the five months following B.P.'s fifteen-month vaccinations). Dr. Harum also included in her initial notes that B.P. had regressed after placement of his tympanostomy tubes "coincident with the period of illness following vaccines" (Ex. 5 at 38), even though B.P.'s tubes were placed in December 2010 – almost six months before the fifteen-month-old visit – and contrary to the Popes's other representations that the fifteen-month-old visit demarcated the change in B.P.'s development. Ex. 3 at 37-39, 49-51; Ex. 9 at 1-2.

On examination, Dr. Harum observed that B.P. demonstrated a normal interest in toys and had good core stability but poor eye contact. Ex. 5 at 40. Dr. Harum assessed his language ability at the fifteen-month level. *Id*. On the Gilliam Autism Rating Scale (based on a questionnaire that Petitioner completed), B.P. had an autism index of 76, indicating possible autism, although Dr. Harum felt that the prior diagnosis, coupled with B.P.'s purported (but uncorroborated by the contemporaneous medical record) "history of encephalopathic regression into autistic behaviors," made it appropriate to diagnose B.P. with autistic regression, moderate language delay, and inflammatory encephalopathy. *Id*.

Dr. Harum subsequently ordered some genetic testing (including a chromosomal microarray, Fragile X testing, and karyotyping), but the results returned in August 2012 were normal. Ex. 5 at 90, 113-16. B.P. returned to Dr. Harum for a follow-up visit on September 6, 2012. *Id*. at 36. Dr. Harum noted at this time that "[a] review of the laboratory data suggests that there are deficits in mitochondrial function and accumulation of lactic acid." *Id*. (referencing Ex. 5 at 96, 98). During another follow-up visit on September 24, 2012, Dr. Harum noted that additional laboratory results indicated an immunoglobulin G ("IgG") deficiency,[8] elevated white blood cell count with lymphocytosis, and persistent markers of mitochondrial dysfunction, such

[7] For example, the Popes informed Dr. Harum that B.P. had received the MMR, Hep A, Varicella, and flu vaccines at his fifteen-month-old visit, when in fact B.P. had received those three months before, on February 23, 2011, when he was one year old. Ex. 9 at 1-2. B.P. actually received only the DTaP and PCV vaccines at fifteen months of age. *Id.* at 3; Ex. 3 at 39.

[8] IgG is a glycoprotein that functions as an antibody. *Dorland's* at 919. An IgG deficiency makes an individual more prone to infections. *IgG Deficiencies,* Health Library, Johns Hopkins Medicine, http://www hopkinsmedicine.org/healthlibrary/conditions/allergy_and_asthma/igg_deficiencies_134,109 (last visited Apr. 4, 2017).

as increased creatine kinase levels.[9] Ex. 5 at 34. She prescribed prednisone "to halt cerebral inflammation," and noted that B.P. was likely an excellent candidate for IVIG treatment, although the notes do not explain her basis for her recommendation. *Id*. at 34-35.

Dr. Harum saw B.P. several times between October 2012 and January 2013. *See generally* Ex. 5 at 24-35. She maintained throughout this time that her treatments were effective and appropriately targeted at the alleged sources of B.P.'s developmental problems, based upon her apparent assumption that B.P. suffered from some kind of underlying immune dysfunction. But other contemporaneous treaters disagreed. For example, Joseph Roberts, M.D., evaluated B.P. at Dr. Harum's request on November 12, 2012, at the Duke University Hospital Pediatric Allergy and Immunology Department to assess B.P.'s recurrent infections and their possible etiology. Ex. 23 at 7-12. At that time, Dr. Roberts reviewed all of B.P.'s prior lab work and ordered some additional testing as well. After the new testing was completed and considered, Dr. Roberts determined – contrary to Dr. Harum – that B.P.'s lab "results demonstrate that he has normal antibody function and IVIG is not indicated." *Id*. at 11. He also opined that B.P.'s "mildly decreased IgG level [was] likely due to transient hypogammaglobulinemia[10] of infancy, which [he] would expect to resolve over time." *Id*. Dr. Roberts recommended that B.P.'s total IgG level be reassessed in six months, but B.P. was never brought back to Dr. Roberts for a follow-up visit. *Id*.; Ex. 16 at 1.

Dr. Harum nevertheless continued to propose treatments for B.P. based upon the supposition that he possessed some form of immune dysfunction that his immunizations had affected. Dr. Harum also began to express the opinion that B.P.'s IgG deficits were linked to mitochondrial insufficiency[11] (in contrast to Dr. Roberts's view that any IgG deficiencies were merely transient). *See, e.g.,* Ex. 5 at 29. She recommended treatment with subcutaneous immunoglobulin therapy (Hizentra), which B.P. started on February 1, 2013. *Id*. at 22, 69; *see also* Ex. 16 at 1. On March 8, 2013, Dr. Harum wrote a letter recommending that B.P. continue to receive home-based services until his IgG counts were in the normal range and proposed

[9] Creatine kinase is an enzyme that catalyzes the phosphorylation of creatine by adenosine triphosphate ("ATP") to form phosphocreatine. The reaction stores the energy of ATP as phosphocreatine in muscle and brain tissue and holds the muscle concentration of ATP nearly constant during the initiation of exercise. *Dorland's* at 429. Increased creatine kinase level can sometimes suggest the presence of a mitochondrial dysfunction or other metabolic disease. *See, e.g.*, *Madariaga v. Sec'y of Health & Human Servs.*, No. 02-1237V, 2015 WL 6160215, at *21, 46 (Fed. Cl. Spec. Mstr. Sept. 26, 2015).

[10] Hypogammaglobulinemia refers to the condition of abnormally low levels of all classes of immunoglobulins in the blood. *Dorland's* at 901.

[11] As discussed in greater detail below, a mitochondrial disorder is caused by mutations or dysfunction of mitochondrial DNA. *Dorland's* at 539. The disorder affects tissues with a high rate of oxidative metabolism, including the brain and peripheral nervous system, and (through hampering the body's cellular energy production systems) can result in encephalopathy, peripheral neuropathy, vision and hearing deficits, muscle pain and weakness, and developmental delays. *Id.*

additional Hizentra injections as well. Ex. 5 at 69. She did note, however, that B.P. was still experiencing symptoms of autism (such as stimming) or immune deficiency (ongoing and repeated upper respiratory infections) despite her recommended treatments. *Id*. Dr. Harum treated B.P. for the remainder of 2013, during which time her initial diagnosis remained consistent.[12] Ex. 8 at 1-14.

Evidence of Purported Mitochondrial Dysfunction

At some time late in the fall of 2013, Mrs. Pope sought an evaluation of B.P. from Richard Frye, M.D., at Arkansas Children's Hospital.[13] In December 2013, Dr. Frye ordered a buccal swab[14] enzyme analysis intended to measure B.P.'s mitochondrial function. Ex. 14 at 1. The result of this test was deemed generally normal, indicating at worst a moderate deficiency in respiratory complex I activity that was not considered definitive. Ex. 11 at 1; Ex. 16 at 2. Other laboratory testing performed while B.P. was under Dr. Frye's care demonstrated that B.P.'s amino acids, creatine kinase, and urine organic acids levels were all normal. Ex. 11 at 2-5. There was evidence of a single abnormal acylcarnitine elevation in C3 dicarboxylic acid (Ex. 17 at 1), but Dr. Dwight Koeberl, a Duke Hospital geneticist who later evaluated B.P. in April 2014, characterized this test result as "likely secondary to normal variation in metabolism," and therefore of no clinical significance. Ex. 16 at 2. Genetic testing for MECP2 and congenital disorders of glycosylation were also negative. *Id.*

Despite the above, Petitioner and certain of B.P.'s treaters pressed on with their theory that some underlying (but previously-undiscovered) mitochondrial dysfunction was partly to blame for B.P.'s developmental problems. Thus, on December 13, 2013, Dr. Frye wrote a

[12] For example, on December 15, 2013, Dr. Harum described B.P.'s condition as follows:

> [B.P.] presented with the typical features of encephalopathic regression into autism following a seemingly normal course of infantile development. Prior to this rather acute onset of regression, he suffered many infections, food allergies, reflux, and chronic yeast dermatitis. He received many antibiotics and respiratory treatments and routine immunizations. Surgery for placement of [tympanostomy tubes] at 15 months, coincident with an illness and vaccines corresponded in time to the onset of encephalopathy.

Ex. 10 at 1. Additionally, she maintained that B.P.'s immune system was "greatly compromised by an abnormal complement of intestinal bacteria, and by the plethora of markers suggesting a mitochondrial disorder." *Id*.

[13] Dr. Frye has previously testified on behalf of petitioners in the Vaccine Program in other cases involving alleged mitochondrial disorders, but he has not submitted opinions in Vaccine Program cases since moving to his current position at Arkansas Children's Hospital, nor did he offer an opinion in this case. *See, e.g., Bast v. Sec'y of Health & Human Servs.*, No. 01-565V, 2012 WL 6858040 (Fed. Cl. Spec. Mstr. Dec. 20, 2012), *mot. for review den'd*, 117 Fed. Cl. 104 (2014). Many Program petitioners claiming that their child possessed some underlying mitochondrial disorder that was exacerbated by a vaccine have consulted with Dr. Frye. *See, e.g., R.V. v. Sec'y of Health & Human Servs.*, No. 08-504V, 2016 WL 3882519 (Fed. Cl. Spec. Mstr. Feb. 19, 2016), *mot. for review den'd*, 127 Fed. Cl. 136 (Fed. Cl. July 1, 2016), *appeal dismissed*, No. 16-2400 (Fed. Cir. Oct. 26, 2016); *Bast*, 2012 WL 6858040.

[14] A buccal swab is a swab of the cheek intended to collect bacteriological material. *See Dorland's* at 257, 1813.

"Telemedicine Note" based on his evaluation of B.P.'s purported "developmental encephalopathy." Ex. 17 at 1-2. That letter confirmed the generally inconclusive testing results regarding possible mitochondrial dysfunction (beyond the single buccal swab analysis results), but made no assertion as to a proper diagnosis. *Id.* at 1. After reviewing the unsuccessful treatments B.P. had undergone over the past months (such as vitamin courses or the trial of IVIG that resulted in a bad febrile reaction that seemed to worsen his symptoms), Dr. Frye recommended that B.P. have mitochondrial DNA sequencing and nuclear DNA sequencing. *Id*. Such mitochondrial DNA testing was performed in 2014, but it did not identify any pathogenic or suspicious variants. Ex. 28 at 3. A comprehensive sequence analysis of nuclear mitochondrial genes was normal, except for one heterozygous variant (NRXN1) of uncertain significance. Ex. 20 at 1.

On April 21, 2014, B.P. returned to Duke for a "genetic evaluation for mitochondrial disease associated with autism" with Dr. Koeberl. Ex. 16 at 1-9. The records from that visit set forth B.P.'s history as provided by his parents, who repeated their view that B.P. had experienced developmental regression shortly after his twelve-month vaccinations when he purportedly lost words, with other behavioral changes evident at fifteen months. *Id*. at 1. B.P.'s parents further reported that it was Dr. Harum who first mentioned in October 2012 that B.P. might have possible mitochondrial dysfunction. *Id*.

Dr. Koeberl reviewed all of the genetic and metabolic laboratory evaluations to date, which largely concluded that B.P.'s results were normal, and recommended additional testing. Ex. 16 at 2-3, 9-10. Subsequent testing for blood lactate, uric acid, and urine organic acids levels was also normal, however, and there was no evidence of a congenital disorder of glycosylation or a defect of creatine synthesis or transport. *Id*. at 10-19. In light of such results, although Dr. Koeberl allowed for the possibility that B.P.'s clinical presentation "could be caused by a mitochondrial disorder," the records from this examination do not reflect that Dr. Koeberl ever made such a diagnosis. *Id.* at 8-9.

Subsequent Evaluations of B.P.'s Condition and its Possible Etiology

B.P. continued to be followed by Dr. Harum in 2015 and 2016 for his autism, but attempts to identify the source of his developmental symptoms produced inconclusive results. *See generally* Exs. 27, 31-32, 37, 41-42, 44, 51. For example, an ambulatory electroencephalogram ("EEG") performed in January 2015 was normal. Ex. 24 at 1. Whole exome sequencing was also ordered, but it did not detect any clinically significant variants or a genetic explanation for B.P.'s autism or speech delay. *Id.*; Ex. 30 at 1-2. Thus, an Autism Multispecialty Clinic patient summary phone note from January 28, 2015, reflects the predominating view of B.P.'s treaters at the time that the etiology of B.P.'s autism spectrum disorder ("ASD") remained unclear. Ex. 28 at 1.

On March 26, 2015, B.P. was evaluated by Francis Kendall, M.D.[15] Ex. 25 at 1-7. At this visit, Mrs. Pope again misreported B.P.'s history of regression following immunizations with fevers at twelve- and fifteen-months of age. *Id*. at 1. Dr. Kendall, relying upon the recited medical history, noted that "[b]ased on his history of regressive autism associated with fever[,] several evaluating physicians, including a neurodevelopmental pediatrician, felt he had features of mitochondrial disease . . ." *Id.* at 1-2. Yet these records suggest that Dr. Kendall was reluctant to embrace the diagnosis, characterizing B.P. merely "as a *possible* mito[chondrial] patient." *Id*. at 5 (emphasis added). Overall, this record establishes that Dr. Kendall's assessment was heavily dependent on assumptions about B.P.'s history and prior treatment assessments (which in turn were also based on Petitioner's assertions), rather than her own objective findings or the test results set forth in B.P.'s medical history.

By June 2015, B.P. was again receiving Hizentra infusions. Ex. 31 at 6-11; Ex. 32 at 1-4; Ex. 39 at 5-9. B.P. saw Dr. Kendall in December 2015 for a follow-up visit. Ex. 43 at 1-5. In the interim, B.P. was reported to be experiencing intermittent ataxia and had several eye infections despite the weekly Hizentra infusions intended to stop these infections (based on Dr. Harum's supposition that they were a product of immune system dysfunction). *Id*. After examination, Dr. Kendall reiterated her prior, inconclusive assessment of B.P. as "possible" for mitochondrial dysfunction. *Id.*

On February 1, 2016, B.P. was again evaluated for mitochondrial disorder or dysfunction, this time by a pediatric neurologist, Sasidharan Taravath, M.D. Ex. 46 at 6-11. Dr. Taravath acknowledged that the clinical diagnosis of a mitochondrial myopathy for B.P. had never been proven "either by DNA test or muscle biopsy." *Id*. at 6-7. After examination, he concluded that a diagnosis of mitochondrial myopathy was only "possible." *Id*. at 10. That same month and into March 2016, an urologist and nephrologist at Duke also evaluated B.P. for reported hematuria and proteinuria. Ex. 48 at 1-11; Ex. 50 at 3-13. A urinalysis at that time was normal, as was a renal bladder ultrasound. *Id.* The nephrologist found that B.P. "has no renal/urinary abnormality." Ex. 50 at 11.[16]

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[15] Like Dr. Frye, Dr. Kendall has frequently testified on behalf of petitioners in other Vaccine Program cases involving autism and/or an alleged mitochondrial disorder, although she did not offer an opinion in this case. *See, e.g., R.K. v. Sec'y of Health & Human Servs.*, No. 03-632V, 2015 WL 10936124 (Fed. Cl. Spec. Mstr. Sept. 28, 2015), *mot. for review den'd*, 125 Fed. Cl. 57 (2016), *aff'd*, No. 16-1609 (Fed. Cir. Dec. 9, 2016); *R.V.*, 2016 WL 3882519; *H.L. v. Sec'y of Health & Human Servs.*, No. 10-197V, 2016 WL 3751848 (Fed. Cl. Spec. Mstr. Mar. 17, 2016), *mot. for review den'd*, 129 Fed. Cl. 165 (2016); *appeal docketed*, No. 17-1218 (Fed. Cir. Nov. 16, 2016); *Holt v. Sec'y of Health & Human Servs.*, No. 05-136V, 2015 WL 4381588 (Fed. Cl. Spec. Mstr. June 24, 2015), *appeal docketed* (Fed. Cl. July 23, 2015).

[16] Petitioner has continued to file additional records since filing her brief in opposition on November 14, 2016. *See* ECF Nos. 55, 57-59 (Exs. 62-72). These records pertain to recent medical visits from the end of 2016 to 2017, including updated lab results, updated records from Duke Children's Health Center ENT, and records from Duke Eye Center. *See* Exs. 70-72. I have reviewed these recently filed records in detail. However, the updated records do

II. EXPERT REPORTS

A. Dr. Karen Harum

Dr. Harum, one of B.P.'s aforementioned treaters, has offered an opinion in this case in support of Petitioner's causation theory. *See generally* Report, dated August 3, 2015 (ECF No. 30-1) (Ex. 33) ("Harum Rep.").

As her CV indicates, Dr. Harum has a private clinical practice as a pediatrician at the Clinic for Special Children in Wilmington, North Carolina. *See* ECF No. 30-2 (Ex. 34) ("Harum CV"), at 1. She is board certified in pediatrics with a certification in neurodevelopmental disabilities. *Id* at 3. Dr. Harum received her M.D. from the University of Miami School of Medicine in 1987 and completed a residency in the Department of Pediatrics at the University of Miami School of Medicine from 1988-1991. *Id.* at 2. Prior to her current position, Dr. Harum was a clinical assistant professor at the Eastern Carolina School of Medicine and an instructor at the Kennedy Krieger Institute Department of Pediatrics at the Johns Hopkins University School of Medicine, where she also completed her fellowship and post-doctoral fellowship. *Id*. at 1-2. Dr. Harum's CV lists approximately eight peer-reviewed articles that were published between 1997 and 2002, along with three book chapters and seven abstracts (*id*. at 4), although she has "not written any articles relevant to the specific issues in this case." Harum Rep. at 1.

Dr. Harum's report does not set forth, in the usual sense (as far as Vaccine Program cases go), an opinion as to how the vaccines that B.P. received in May 2011 produced his alleged developmental regression or ASD, or whether they could do so generally. Rather, it summarizes information contained in Petitioner's exhibits 1 through 22. *See generally* Harum Rep. at 1-5. Although it recites facts that Dr. Harum and Petitioner likely believe support Petitioner's claim, the report contains very little in the way of expert opinion or analysis explaining how the vaccines at issue purportedly caused B.P.'s developmental problems – nor does it offer any medical or scientific literature in support of its presumed opinions.

For example, Dr. Harum notes that Petitioner's consultation with Dr. Kendall in 2015 "suggests that mitochondrial deficits are present," and she contends that finding is corroborated by the buccal swab analysis obtained in 2013 by Dr. Frye that suggested a moderate deficiency of complex I activity. Harum Rep. at 4. But this merely restates what the records (arguably) show – it does not stand as independent or interpretive analysis. Dr. Harum's report therefore does not set forth an explanation for how B.P.'s autism is possibly linked to his vaccinations, based upon Dr. Harum's expertise in the relevant field, nor does it provide any explanation or

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not contain any information contrary to what was previously filed, and do not otherwise cause me to change my analysis, and therefore they are not discussed at length herein.

theory as to how the alleged vaccines were a substantial factor in bringing about B.P.'s autism – although it can reasonably be assumed from the report (and as reflected in the treatment history) that she holds that opinion.

B. Dr. Marcel Kinsbourne

Dr. Kinsbourne prepared Petitioner's other expert report, which attempts to provide the explanation of a link between B.P.'s regression/autism and his PCV and DTaP vaccinations that is missing from Dr. Harum's report. *See* Report, dated September 30, 2015 (ECF No. 32-1) (Ex. 35) ("Kinsbourne Rep.").

As his CV indicates, Dr. Kinsbourne is board certified in pediatrics. ECF No. 32-2 (Ex. 36) ("Kinsbourne CV"), at 1. He received his medical degree in England, and he has been licensed to practice medicine in North Carolina since 1967. *Id*. From 1967 to 1974, Dr. Kinsbourne served as an associate professor in pediatrics and neurology and a senior research associate at Duke University Medical Center before holding a series of academic positions, including professorships in pediatrics, neurology, and psychology. *Id*. at 2. His clinical experience includes serving as a senior staff physician in Ontario from 1974-1980, and a clinical associate in neurology at Massachusetts General Hospital from 1981-1991, although (as noted in other cases) many years have passed since he regularly saw patients. He has published several articles examining autism (Kinsbourne CV at 15, 21-22, 27), and he is on the editorial board of several journals that deal with the brain, such as Brain and Cognition and Brain Research. Kinsbourne CV at 3.

Dr. Kinsbourne opines that B.P. suffers from an "autistic type" mitochondrial encephalopathy that was produced by his fifteen-month DTaP and PCV vaccinations, which significantly aggravated a pre-existing "asymptomatic mitochondrial deficiency." Kinsbourne Rep. at 3-6. In particular, he proposes that the May 2011 vaccinations interfered with B.P.'s subclinical mitochondrial dysfunction (not discovered in B.P. until years later) by increasing oxidative stress, which then clinically manifested as autistic regression. *Id.* at 4-5. Dr. Kinsbourne does not propose that these vaccines directly caused B.P.'s developmental problems, but that they significantly aggravated his alleged underlying mitochondrial disorder. *See id*. at 6.

In his report, Dr. Kinsbourne explains that mitochondria, the organelles in the body's cells responsible for energy production, are vulnerable to oxidative stress. Vaccines can generate oxidative stress by activating the immune system, producing proinflammatory cytokines[17] which can tip the balance of reactive oxygen species, resulting in cell damage and (later) autistic

[17] Cytokine is a generic term for non-antibody proteins released by one cell population on contact with specific antigen, which act as intercellular mediators, as in the generation of an immune response. *Dorland's* at 466. Proinflammatory signifies that these cytokines are capable of stimulating inflammation. *Id.* at 1523.

symptoms once the damage arrives in the brain. Kinsbourne Rep. at 5-6. The report does not explain, however, how much oxidative stress is generated by vaccination generally (or the vaccines in question specifically), nor does it propose what level of oxidative stress is necessary to cross the "tipping point" to cause clinical disease manifesting as autism or how long this cytokine production would be maintained post-vaccination. Nor, based on his CV, does it appear that Dr. Kinsbourne has the specific experience in the fields of immunology, mitochondrial function, or metabolic disorders to opine credibly on these topics, despite his pediatric and neurologic expertise.

Dr. Kinsbourne's opinion is premised upon several factual assumptions, including that B.P. (1) suffered from a "mitochondrial encephalopathy, autistic type"; (2) regressed after his fifteen-month vaccinations on May 11, 2011; and (3) had a preexisting underlying "genetically based susceptibility" in cellular energy metabolism "caused by his deficiency in the function of mitochondrial chain complex 1." Kinsbourne Rep. at 3-5. The foundation for these assumptions, however, appears to be Petitioner's own statements about B.P.'s condition rather than the medical records, particularly with respect to onset of his developmental problems – a fact Dr. Kinsbourne admits. *Id.* at 3 ("the pediatric records do not offer any assistance as to when [B.P.] began to suffer autistic regression").

The timing of B.P.'s purported regression is dispositive to Dr. Kinsbourne's opinion, as is B.P.'s alleged mitochondrial susceptibility/dysfunction. *See, e.g.,* Kinsbourne Rep. at 3 ("[w]hether the DTaP and Prevnar vaccinations constitute the risk factor that transformed the disorder from a subclinical to a clinical level depends in the first instance on when the autistic regression began"). To support his opinion, Dr. Kinsbourne references approximately eight studies or articles, although not all were filed in this action.[18]

Overall, Dr. Kinsbourne opined that vaccinations activate immune system cells, which in turn generate oxidative stress. Therefore, he believed it to be medically reasonable that mitochondria could be stressed by one or more vaccinations and cause, among other things, a mitochondrial encephalopathy with autistic features. Kinsbourne Rep. at 6.

C. Dr. Bruce Cohen

Dr. Cohen provided an expert report for Respondent. Dr. Cohen is board certified in pediatrics and neurology, with special competence in child neurology. Report, dated March 14, 2016 (ECF No. 40-1) (Ex. A) ("Cohen Rep."), at 1; ECF No. 40-2 (Ex. B) ("Cohen CV"), at 2.

[18] In fact, Petitioner only filed two of the articles referenced in Dr. Kinsbourne's report – Poling et al., *Developmental Regression and Mitochondrial Dysfunction in a Child with Autism*, 21 J. Child Neurol. 170: 170-172 (2006) (filed as Ex. 63) ("Poling"), and Shoffner et al., *Fever Plus Mitochondrial Disease Could be Risk Factors for Autistic Regression*, 25 J. Child Neurol. 429: 429-434 (2010) (filed as Ex. 64) ("Shoffner").

Previously, Dr. Cohen completed his pediatric residency and a two-year fellowship at Children's Hospital of Philadelphia, and a pediatric neurology residency at Columbia Presbyterian Medical Center. Cohen Rep. at 1. He also worked for more than twenty-one years at The Cleveland Clinic practicing as a child neurologist specializing in children and adults with brain tumors and mitochondrial disease. *Id*. Dr. Cohen has received numerous honors and awards, and he has also served on various advisory groups, editorial boards, and review panels over the course of his career. Cohen CV at 2-3. He is a member of several professional societies, including the American Academy of Neurology, Child Neurology Society, Mitochondrial Research Society, and the Mitochondrial Medicine Society. *Id*. at 2. He currently serves as the Director of the NeuroDevelopmental Science Center and the Director of Neurology at the Children's Hospital Medical Center of Akron, as well as a Professor of Pediatrics at the Northeast Ohio College of Medicine. *Id.* at 1.

Dr. Cohen has demonstrated experience and expertise in the field of mitochondrial disorders and diseases. His peers have elected him to serve in both the areas of mitochondrial medicine and child neurology. Cohen Rep. at 3. He has conducted original peer-reviewed research and written extensively in the field of mitochondrial disease, recently co-authoring a textbook of mitochondrial medicine. *Id*. Today, Dr. Cohen has an active clinical practice as a child neurologist specializing in mitochondrial disease. *Id.* at 1-2. As part of his clinical practice, Dr. Cohen routinely orders testing to evaluate and diagnose mitochondrial disease. *Id.* He has also evaluated hundreds of children with developmental delays or regression and autism spectrum disorders. *Id*. at 1.

Based on a careful evaluation of the evidence, including the various test results from B.P.'s treatment by Drs. Frye and Harum, Dr. Cohen opined that B.P. does not have a mitochondrial illness, dysfunction, or disease, nor did he suffer an encephalopathy or regression temporally following either his twelve-month or fifteen-month vaccinations. Cohen Rep. at 13-22. Rather, B.P. more likely suffers from idiopathic autism typical of many children, as reflected in his clinical course established by the contemporaneous medical records. *Id.* at 13, 14. Dr. Cohen thus disagrees with Dr. Kinsbourne that B.P. suffered from a vaccine-related encephalopathy or that any of his vaccinations was a substantial factor in the development of his autism. *Id*. at 21-22.

In support of his opinion, Dr. Cohen provided a very careful and detailed explanation of how an experienced mitochondrial specialist investigates for a possible mitochondrial problem, citing to generally-accepted diagnostic criteria and supporting medical literature. *See* Cohen Rep. at 13-19. At the outset, Dr. Cohen observed that B.P. lacked any of the presenting clinical criteria that would "be part of the primary mitochondrial phenotype," setting forth a lengthy list of several clinical criteria (for example, MRI evidence of brain lesions) that were absent from B.P.'s records. *Id.* at 14. He also noted that B.P.'s presentation as detailed in the medical records

was not consistent with any recognized form of mitochondrial disease, like Leigh disease[19] or MELAS.[20] *Id.* Dr. Cohen agreed (as Dr. Kinsbourne proposed) that "autism can be seen in children who also have mitochondrial disorders," but he added that not only have mitochondrial diseases and dysfunctions not been causally linked to autism, but also that autistic children found to possess a mitochondrial disorder "have additional clinical features or diagnostic biochemical-genetic-histological features" absent herein. *Id.*

Given the lack of obvious and compelling direct evidence of mitochondrial disease or disorder in this case, Dr. Cohen noted that determining if a patient such as B.P. truly possessed any kind of mitochondrial dysfunction would require one of two kinds of evidence: genetic testing proof (absent here, as the aforementioned factual history revealed), or lab tests confirming the existence of mitochondrial problems. Cohen Rep. at 14. Dr. Cohen's report explained in great detail the nature of these tests and their advantages and disadvantages – as well as why, in this case, the testing and evaluations of B.P. did not support the diagnosis. *Id.* at 14-18. In Dr. Cohen's opinion, the buccal swab analysis, genetic testing, and other laboratory results from the medical treatment records in this case did not provide reliable support for the conclusion that B.P. suffered from any likely mitochondrial disease or dysfunction. *Id.* at 16-18. Nor did he accept the view that the frequency, type, or severity of B.P.'s childhood illnesses during the period of time he was receiving vaccinations were abnormal for healthy children, as none of the illnesses were life-threatening or resulted in hospitalizations. *Id.* Further, there were no emergency department records associated with these visits, suggesting to Dr. Cohen that all of the pediatric providers were able to deal with the infections, thus confirming their minor character. *Id.*

D. Dr. Frances Kendall

In opposing the pending motion to dismiss, Mrs. Pope represented that she had recently contacted Dr. Kendall (one of B.P.'s treaters as discussed in the medical history section above) about offering an expert opinion in this case (specifically as to whether B.P. suffered from some underlying mitochondrial disease or disorder), and that she intended to file it "as soon as we receive it." Opp. at 22. To date, however (and now months after the filing of Petitioner's opposition brief) no such report has been filed, nor has Petitioner filed a status report or motion of any kind requesting that I defer action on Respondent's motion until the filing of such a report.

[19] Leigh disease is a type of subacute necrotizing encephalomyelopathy. *Dorland's* at 1018.

[20] Mitochondrial encephalomyopathy, lactic acidosis, and stroke-like episodes ("MELAS") is a condition that affects particularly the brain, nervous system, and muscles. The symptoms of MELAS often appear in childhood after a period of normal development, and early symptoms may include muscle weakness and pain, headaches, and seizures. *Mitochondrial Encephalomyopathy, Lactic Acidosis, and Stroke-like Episodes*, Genetics Home Reference, U.S. National Library of Medicine, available at: https://ghr.nlm.nih.gov/condition/mitochondrial-encephalomyopathy-lactic-acidosis-and-stroke-like-episodes (last visited April 6, 2017).

III. PROCEDURAL HISTORY

As noted above, this action was initiated in January 2014. Petition at 1. From January 29 through June 25, 2014, Mrs. Pope filed B.P.'s medical records, designated as Exhibits 1 through 17. On August 25, 2014, Respondent filed his Rule 4(c) Report recommending that compensation be denied and the Petition be dismissed. ECF No. 16.

Thereafter, Petitioner undertook to file certain outstanding records identified in the Rule 4(c) Report, and I ordered that she file an expert report in support of her claim. *See* Order, dated Sept. 15, 2014 (ECF No. 17). Six months passed without the filing of such a report, however (although Petitioner did receive one extension to act). Then, in March 2015 (at her second deadline for filing an expert report), Mrs. Pope requested that this matter be stayed in light of the pending Federal Circuit decision in a different case (which has since been decided), *Paluck v. Sec'y of Health & Human Servs.,* 786 F.3d 1373 (Fed. Cir. 2015), which she argued could be dispositive of this matter. Motion, dated March 31, 2015 (ECF No. 24).

In response, I noted that there were significant facial disparities between the facts of this case and *Paluck*, and therefore I did not accept at face value Petitioner's contention that the disposition of that case bore on the resolution of this matter (which appeared, based on the medical records, far more akin to the vast majority of autism injury cases heard in the Vaccine Program over the past ten years).[21] Order, dated Apr. 21, 2014 (ECF No. 25). I did, however, agree to provide Petitioner even more time to file an expert report, setting the end of August as the deadline to do so. *Id.* at 2.

On August 31, 2015, Petitioner filed Dr. Harum's report. She also indicated at that time that she planned to file an additional expert report but needed more time to do so, and I granted that request. On October 1, 2015, Petitioner filed Dr. Kinsbourne's report. I thereafter ordered

[21] In *Paluck*, the Federal Circuit affirmed the Court of Federal Claims's determination that a special master had erred in denying compensation to petitioners claiming (in a non-Table case) that the MMR, varicella, and pneumococcal vaccines significantly aggravated their child's mitochondrial disease, resulting in severe neurodegeneration. However, that case is facially, and procedurally, distinguishable. The vaccinated child (a one-year old) in *Paluck* had experienced a persistently high fever in the two to seven days immediately after receiving the vaccines and was soon thereafter diagnosed with possible neurologic problems confirmed by MRI results, among other things. *Paluck*, 786 F.3d at 1376. This is obviously different from the present circumstances, in which the record does not reveal any immediate reaction (outside of Petitioner's individual allegations). Moreover, in *Paluck* the child's mitochondrial disease was not a contested fact, as here. Rather, Respondent's expert admitted, during the initial hearing and while under cross-examination, that the theory had plausibility. And later in the case's history (as observed by the special master presiding over the case after it was remanded to him the first time), Respondent effectively dropped the issue entirely. *Paluck v. Sec'y of Health & Human Servs*., No. 07-889V, 2013 WL 2453747, at *42 (Fed. Cl. Spec. Mstr. May 10, 2013) (special master noting that even though Respondent had not made an "outright concession" of petitioners' theory, he "did not present any substantive argument regarding prong one of *Althen* in any of [his] post-remand briefs"), *mot. for review granted*, 113 Fed. Cl. 210 (2013), *aff'd*, 786 F.3d 1373 (Fed. Cir. 2015).

Respondent to file an expert report of his own, and Respondent subsequently filed Dr. Cohen's report on March 15, 2016.

In April 2016, I held a status conference with the parties after reviewing the case record and each side's expert reports in greater detail. *See generally* Order, dated April 4, 2006 (ECF No. 41). By this point, it was evident that Petitioner's causation theory relied on the determination that B.P. had an underlying mitochondrial disease or disorder exacerbated by his vaccinations, which thereby precipitated an encephalopathic reaction that resulted in developmental regression and B.P.'s autism diagnosis. But it was equally evident that the medical record (which contained the most probative and reliable evidence as to B.P.'s history) did not support such a conclusion. It also was clear that the theory being advanced in this case was little different from those repeatedly rejected in other Vaccine Act cases, many of which had been tried at an entitlement hearing. I thus informed Petitioner that I had serious concerns about her claim's viability, in light of both the history of Program claims asserting a similar theory, as well as my own experience deciding similar cases in which mitochondrial diseases were alleged to have been linked to an autism injury mediated by vaccination.

Given the above, I proposed that, in lieu of a hearing, the parties brief Petitioner's claim, and I set a schedule for so doing. Order, dated April 4, 2016, at 2. Over several months, the parties filed their respective briefs, as referenced at the outset of this decision. The matter is now fully briefed and ripe for resolution.

IV. APPLICABLE LEGAL STANDARDS

A. Claimant's Burden in Vaccine Program Cases

To receive compensation in the Vaccine Program, a petitioner must prove either: (1) that he suffered a "Table Injury" – i.e., an injury falling within the Vaccine Injury Table – corresponding to one of the vaccinations in question within a statutorily prescribed period of time or, in the alternative, (2) that his illnesses were actually caused by a vaccine (a "Non-Table Injury"). *See* Sections 13(a)(1)(A), 11(c)(1), and 14(a), as amended by 42 C.F.R. § 100.3; § 11(c)(1)(C)(ii)(I); *see also Moberly v. Sec'y of Health & Human Servs*., 592 F.3d 1315, 1321 (Fed. Cir. 2010); *Capizzano v. Sec'y of Health & Human Servs*., 440 F.3d 1317, 1320 (Fed. Cir. 2006).[22] In this case, Petitioner does not assert a Table claim.

[22] Decisions of special masters (some of which I reference in this ruling) constitute persuasive but not binding authority. *Hanlon v. Sec'y of Health & Human Servs.*, 40 Fed. Cl. 625, 630 (1998). By contrast, Federal Circuit rulings concerning legal issues are binding on special masters. *Guillory v. Sec'y of Health & Human Servs.*, 59 Fed. Cl. 121, 124 (2003), *aff'd*, 104 F. App'x 712 (Fed. Cir. 2004); *see also Spooner v. Sec'y of Health & Human Servs.*, No. 13-159V, 2014 WL 504728, at *7 n.12 (Fed. Cl. Spec. Mstr. Jan. 16, 2014).

For both Table and Non-Table claims, Vaccine Program petitioners bear a "preponderance of the evidence" burden of proof. Section 13(1)(a). That is, a petitioner must offer evidence that leads the "trier of fact to believe that the existence of a fact is more probable than its nonexistence before [he] may find in favor of the party who has the burden to persuade the judge of the fact's existence." *Moberly*, 592 F.3d at 1322 n.2; *see also Snowbank Enter. v. United States*, 6 Cl. Ct. 476, 486 (1984) (mere conjecture or speculation is insufficient under a preponderance standard). Proof of medical certainty is not required. *Bunting v. Sec'y of Health & Human Servs*., 931 F.2d 867, 873 (Fed. Cir. 1991). In particular, a petitioner must demonstrate that the vaccine was "not only [the] but-for cause of the injury but also a substantial factor in bringing about the injury." *Moberly*, 592 F.3d at 1321 (quoting *Shyface v. Sec'y of Health & Human Servs*., 165 F.3d 1344, 1352-53 (Fed. Cir. 1999)); *Pafford v. Sec'y of Health & Human Servs*., 451 F.3d 1352, 1355 (Fed. Cir. 2006). A petitioner may not receive a Vaccine Program award based solely on his assertions; rather, the petition must be supported by either medical records or by the opinion of a competent physician. Section 13(a)(1).

In attempting to establish entitlement to a Vaccine Program award of compensation for a Non-Table claim (which is the kind of claim asserted in this matter), a petitioner must satisfy all three of the elements established by the Federal Circuit in *Althen v. Sec'y of Health & Human Servs.,* 418 F.3d 1274, 1278 (Fed. Cir. 2005): "(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury."

Each of the *Althen* prongs requires a different showing. Under *Althen* prong one, petitioners must provide a "reputable medical theory," demonstrating that the vaccine received *can cause* the type of injury alleged. *Pafford*, 451 F.3d at 1355-56 (citations omitted). To satisfy this prong, the petitioner's theory must be based on a "sound and reliable medical or scientific explanation." *Knudsen v. Sec'y of Health & Human Servs.*, 35 F.3d 543, 548 (Fed. Cir. 1994). Such a theory must only be "legally probable, not medically or scientifically certain." *Id*. at 549.

Petitioners may satisfy the first *Althen* prong without resort to medical literature, epidemiological studies, demonstration of a specific mechanism, or a generally accepted medical theory. *Andreu v. Sec'y of Health & Human Servs.*, 569 F.3d 1367, 1378-79 (Fed. Cir. 2009) (citing *Capizzano*, 440 F.3d at 1325-26). Special masters, despite their expertise, are not empowered by statute to conclusively resolve what are essentially thorny scientific and medical questions, and thus scientific evidence offered to establish *Althen* prong one is viewed "not through the lens of the laboratorian, but instead from the vantage point of the Vaccine Act's preponderant evidence standard." *Id.* at 1380. Accordingly, special masters must take care not to increase the burden placed on petitioners in offering a scientific theory linking vaccine to injury. *Contreras v. Sec'y of Health & Human Servs.*, 121 Fed. Cl. 230, 245 (2015) ("[p]lausibility . . .

in many cases *may* be enough to satisfy *Althen* prong one" (emphasis in original)). But this does not negate or reduce a petitioner's ultimate burden to establish his overall entitlement to damages by preponderant evidence. *W.C. v. Sec'y of Health & Human Servs.*, 704 F.3d 1352, 1356 (Fed. Cir. 2013) (citations omitted).

The second *Althen* prong requires proof of a logical sequence of cause and effect, usually supported by facts derived from a petitioner's medical records. *Althen*, 418 F.3d at 1278; *Andreu*, 569 F.3d at 1375-77; *Capizzano*, 440 F.3d at 1326; *Grant v. Sec'y of Health & Human Servs.*, 956 F.2d 1144, 1148 (Fed. Cir. 1992). In establishing that a vaccine "did cause" injury, the opinions and views of the injured party's treating physicians are entitled to some weight. *Andreu*, 569 F.3d at 1367; *Capizzano*, 440 F.3d at 1326 ("medical records and medical opinion testimony are favored in vaccine cases, as treating physicians are likely to be in the best position to determine whether a 'logical sequence of cause and effect show[s] that the vaccination was the reason for the injury'") (quoting *Althen*, 418 F.3d at 1280). Medical records are generally viewed as particularly trustworthy evidence, since they are created contemporaneously with the treatment of the patient. *Cucuras v. Sec'y of Health & Human Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993).

However, medical records and/or statements of a treating physician's views do not *per se* bind the special master to adopt the conclusions of such an individual, even if they must be considered and carefully evaluated. Section 13(b)(1) (providing that "[a]ny such diagnosis, conclusion, judgment, test result, report, or summary shall not be binding on the special master or court"); *Snyder v. Sec'y of Health & Human Servs.*, 88 Fed. Cl. 706, 746 n.67 (2009) ("there is nothing . . . that mandates that the testimony of a treating physician is sacrosanct—that it must be accepted in its entirety and cannot be rebutted"). As with expert testimony offered to establish a theory of causation, the opinions or diagnoses of treating physicians are only as trustworthy as the reasonableness of their suppositions or bases. The views of treating physicians should also be weighed against other, contrary evidence also present in the record – including conflicting opinions among such individuals. *Hibbard v. Sec'y of Health & Human Servs.*, 100 Fed. Cl. 742, 749 (2011) (not arbitrary or capricious for special master to weigh competing treating physicians' conclusions against each other), *aff'd*, 698 F.3d 1355 (Fed. Cir. 2012); *Caves v. Sec'y of Health & Human Servs.*, 100 Fed. Cl. 119, 136 (2011), *aff'd*, 463 F. App'x 932 (Fed. Cir. 2012); *Veryzer v. Sec'y of Health & Human Servs.*, No. 06-522V, 2011 WL 1935813, at *17 (Fed. Cl. Spec. Mstr. Apr. 29, 2011), *mot. for review den'd,* 100 Fed. Cl. 344, 356 (2011), *aff'd without opinion*, 475 Fed. App'x 765 (Fed. Cir. 2012).

The third *Althen* prong requires establishing a "proximate temporal relationship" between the vaccination and the injury alleged. *Althen*, 418 F.3d at 1281. That term has been equated to the phrase "medically-acceptable temporal relationship." *Id.* A petitioner must offer "preponderant proof that the onset of symptoms occurred within a timeframe which, given the

medical understanding of the disorder's etiology, it is medically acceptable to infer causation." *Bazan v. Sec'y of Health & Human Servs.*, 539 F.3d 1347, 1352 (Fed. Cir. 2008). The explanation for what is a medically acceptable timeframe must also coincide with the theory of how the relevant vaccine can cause an injury (*Althen* prong one's requirement). *Id*. at 1352; *Shapiro v. Sec'y of Health & Human Servs.*, 101 Fed. Cl. 532, 542 (2011), *recons. den'd after remand*, 105 Fed. Cl. 353 (2012), *aff'd mem.*, 2013 WL 1896173 (Fed. Cir. 2013); *Koehn v. Sec'y of Health & Human Servs*., No. 11-355V, 2013 WL 3214877 (Fed. Cl. Spec. Mstr. May 30, 2013), *mot. for review den'd* (Fed. Cl. Dec. 3, 2013), *aff'd*, 773 F.3d 1239 (Fed. Cir. 2014).

B. Standard for Significant Aggravation Claim

In this matter, besides arguing that the DTaP and/or PCV vaccines caused B.P.'s autism and/or autistic regression, Petitioner also offers a parallel theory that the vaccines significantly aggravated a preexisting condition in B.P. – his purported mitochondrial disease or dysfunction. Where a petitioner so alleges, the *Althen* test is expanded, and the petitioner has additional evidentiary burdens to satisfy. *See generally Loving v. Sec'y of Health & Human Servs*., 86 Fed. Cl. 135, 144 (2009). In *Loving*, the Court of Federal Claims combined the *Althen* test with the test from *Whitecotton v. Sec'y of Health & Human Servs*., 81 F.3d 1099, 1107 (Fed. Cir. 1996), which related to on-Table significant aggravation cases. The resultant "significant aggravation" test has six components, which are:

> (1) the person's condition prior to administration of the vaccine, (2) the person's current condition (or the condition following the vaccination if that is also pertinent), (3) whether the person's current condition constitutes a 'significant aggravation' of the person's condition prior to vaccination, (4) a medical theory causally connecting such a significantly worsened condition to the vaccination, (5) a logical sequence of cause and effect showing that the vaccination was the reason for the significant aggravation, and (6) a showing of a proximate temporal relationship between the vaccination and the significant aggravation.

Loving, 86 Fed. Cl. at 144; *see also W.C. v. Sec'y of Health & Human Servs*., 704 F.3d 1352, 1357 (Fed. Cir. 2013) (holding that "the *Loving* case provides the correct framework for evaluating off-table significant aggravation claims"). In effect, the last three prongs of the Loving test correspond to the three *Althen* prongs.

C. Law Governing Factual Determinations

The process for making determinations in Vaccine Program cases regarding factual issues begins with consideration of the medical records. Section 11(c)(2). The special master is required to consider "all [] relevant medical and scientific evidence contained in the record," including "any diagnosis, conclusion, medical judgment, or autopsy or coroner's report which is contained in the record regarding the nature, causation, and aggravation of the petitioner's illness,

disability, injury, condition, or death," as well as "the results of any diagnostic or evaluative test which are contained in the record and the summaries and conclusions." Section 13(b)(1)(A). The special master is then required to weigh the evidence presented, including contemporaneous medical records and testimony. *See Burns v. Sec'y of Health & Human Servs*., 3 F.3d 415, 417 (Fed. Cir. 1993) (it is within the special master's discretion to determine whether to afford greater weight to contemporaneous medical records than to other evidence, such as oral testimony surrounding the events in question that was given at a later date, provided that such a determination is evidenced by a rational determination).

Medical records that are created contemporaneously with the events they describe are presumed to be accurate and "complete" (i.e., presenting all relevant information on a patient's health problems). *Cucuras*, 993 F.2d at 1528; *Doe/70 v. Sec'y of Health & Human Servs.*, 95 Fed. Cl. 598, 608 (2010) ("[g]iven the inconsistencies between petitioner's testimony and his contemporaneous medical records, the special master's decision to rely on petitioner's medical records was rational and consistent with applicable law"), *aff'd*, *Rickett v. Sec'y of Health & Human Servs*., 468 F. App'x 952 (Fed. Cir. 2011) (non-precedential opinion). This presumption is based on the linked propositions that (i) sick people visit medical professionals; (ii) sick people honestly report their health problems to those professionals; and (iii) medical professionals record what they are told or observe when examining their patients in as accurate a manner as possible, so that they are aware of enough relevant facts to make appropriate treatment decisions. *Sanchez v. Sec'y of Health & Human Servs*., No. 11-685V, 2013 WL 1880825, at *2 (Fed. Cl. Spec. Mstr. Apr. 10, 2013); *Cucuras v. Sec'y of Health & Human Servs*., 26 Cl. Ct. 537, 543 (1992), *aff'd*, 993 F.2d 1525 (Fed. Cir. 1993) ("[i]t strains reason to conclude that petitioners would fail to accurately report the onset of their daughter's symptoms. It is equally unlikely that pediatric neurologists, who are trained in taking medical histories concerning the onset of neurologically significant symptoms, would consistently but erroneously report the onset of seizures a week after they in fact occurred").

Accordingly, if the medical records are clear, consistent, and complete, then they should be afforded substantial weight. *Lowrie v. Sec'y of Health & Human Servs*., No. 03-1585V, 2005 WL 6117475, at *20 (Fed. Cl. Spec. Mstr. Dec. 12, 2005). Indeed, contemporaneous medical records are generally found to be deserving of greater evidentiary weight than oral testimony – especially where such testimony conflicts with the record evidence. *Cucuras*, 993 F.2d at 1528; *see also Murphy v. Sec'y of Health & Human Servs.*, 23 Cl. Ct. 726, 733 (1991), *aff'd*, 968 F.2d 1226 (Fed. Cir.), *cert. den'd, Murphy v. Sullivan*, 506 U.S. 974 (1992) (citing *United States v. United States Gypsum Co.*, 333 U.S. 364, 396 (1947) ("[i]t has generally been held that oral testimony which is in conflict with contemporaneous documents is entitled to little evidentiary weight.")).

However, there are situations in which compelling oral testimony may be more persuasive than written records, such as where records are deemed to be incomplete or inaccurate. *Campbell v. Sec'y of Health & Human Servs*., 69 Fed. Cl. 775, 779 (2006) ("like any norm based upon common sense and experience, this rule should not be treated as an absolute and must yield where the factual predicates for its application are weak or lacking"); *Lowrie*, 2005 WL 6117475, at *19 ("[w]ritten records which are, themselves, inconsistent, should be accorded less deference than those which are internally consistent") (quoting *Murphy v. Sec'y of Health & Human Servs.*, 23 Cl. Ct. 726, 733 (1991), *aff'd per curiam*, 968 F.2d 1226 (Fed. Cir. 1992)). Ultimately, a determination regarding a witness's credibility is needed when determining the weight that such testimony should be afforded. *Andreu*, 569 F.3d at 1379; *Bradley v. Sec'y of Health & Human Servs.*, 991 F.2d 1570, 1575 (Fed. Cir. 1993).

When witness testimony is offered to overcome the presumption of accuracy afforded to contemporaneous medical records, such testimony must be "consistent, clear, cogent, and compelling." *Sanchez*, 2013 WL 1880825, at *3 (citing *Blutstein v. Sec'y of Health & Human Servs*., No. 90-2808V, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998)). In determining the accuracy and completeness of medical records, the Court of Federal Claims has listed four possible explanations for inconsistencies between contemporaneously created medical records and later testimony: (1) a person's failure to recount to the medical professional everything that happened during the relevant time period; (2) the medical professional's failure to document everything reported to her or him; (3) a person's faulty recollection of the events when presenting testimony; or (4) a person's purposeful recounting of symptoms that did not exist. *La Londe v. Sec'y Health & Human Servs*., 110 Fed. Cl. 184, 203-04 (2013), *aff'd*, 746 F.3d 1334 (Fed. Cir. 2014). In making a determination regarding whether to afford greater weight to contemporaneous medical records over contrary testimony, there must be evidence that this decision was the result of a rational determination. *Burns*, 3 F.3d at 417.

D. Analysis of Expert Testimony

Establishing a sound and reliable medical theory often requires a petitioner to present expert testimony in support of his claim. *Lampe v. Sec'y of Health & Human Servs.*, 219 F.3d 1357, 1361 (Fed. Cir. 2000). Vaccine Program expert testimony is usually evaluated according to the factors for analyzing scientific reliability set forth in *Daubert v. Merrell Dow Pharm., Inc*., 509 U.S. 579, 594-96 (1993). *See Cedillo v. Sec'y of Health & Human Servs.*, 617 F.3d 1328, 1339 (Fed. Cir. 2010) (citing *Terran v. Sec'y of Health & Human Servs.*, 195 F.3d 1302, 1316 (Fed. Cir. 1999)). "The *Daubert* factors for analyzing the reliability of testimony are: (1) whether a theory or technique can be (and has been) tested; (2) whether the theory or technique has been subjected to peer review and publication; (3) whether there is a known or potential rate of error and whether there are standards for controlling the error; and (4) whether the theory or technique enjoys general acceptance within a relevant scientific community." *Terran*, 195 F.3d at 1316 n.2 (citing *Daubert*, 509 U.S. at 592-95).

The *Daubert* factors play a slightly different role in Vaccine Program cases than they do when applied in other federal judicial fora (such as the district courts). *Daubert* factors are usually employed by judges (in the performance of their evidentiary gatekeeper roles) to exclude evidence that is unreliable and/or could confuse a jury. In Vaccine Program cases, by contrast, these factors are used in the *weighing* of the reliability of scientific evidence proffered. *Davis v. Sec'y of Health & Human Servs.*, 94 Fed. Cl. 53, 66-67 (2010) ("uniquely in this Circuit, the *Daubert* factors have been employed also as an acceptable evidentiary-gauging tool with respect to persuasiveness of expert testimony already admitted"). The flexible use of the *Daubert* factors to evaluate the persuasiveness and reliability of expert testimony has routinely been upheld. *See, e.g.*, *Snyder*, 88 Fed. Cl. at 742-45. In this matter (as in numerous other Vaccine Program cases), *Daubert* has not been employed at the threshold, to determine what evidence should be admitted, but instead to determine whether expert testimony offered is reliable and/or persuasive.

Respondent frequently offers one or more experts of his own in order to rebut a petitioner's case. Where both sides offer expert testimony, a special master's decision may be "based on the credibility of the experts and the relative persuasiveness of their competing theories." *Broekelschen v. Sec'y of Health & Human Servs.*, 618 F.3d 1339, 1347 (Fed. Cir. 2010) (citing *Lampe*, 219 F.3d at 1362). However, nothing requires the acceptance of an expert's conclusion "connected to existing data only by the *ipse dixit* of the expert," especially if "there is simply too great an analytical gap between the data and the opinion proffered." *Snyder*, 88 Fed. Cl. at 743 (quoting *Gen. Elec. Co. v. Joiner*, 522 U.S. 146 (1997)); *see also Isaac v. Sec'y of Health & Human Servs.*, No. 08-601V, 2012 WL 3609993, at *17 (Fed. Cl. Spec. Mstr. July 30, 2012), *mot. for review den'd*, 108 Fed. Cl. 743 (2013), *aff'd*, 540 Fed. App'x 999 (Fed. Cir. 2013) (citing *Cedillo*, 617 F.3d at 1339).

E. Consideration of Medical Literature

Both parties relied on a few pieces of medical and scientific literature in this case in support of their respective positions. I have reviewed all of the medical literature submitted in this case, although my decision does not discuss each filed article in detail. *Moriarty v. Sec'y of Health & Human Servs.,* No. 2015-5072, 2016 WL 1358616, at *5 (Fed. Cir. Apr. 6, 2016) ("[w]e generally presume that a special master considered the relevant record evidence even though he does not explicitly reference such evidence in his decision") (citation omitted).

F. Determination to Resolve Case without Hearing

I have opted to decide entitlement in this case based on written submissions and evidentiary filings, including the expert reports filed by each side. The Vaccine Act and Rules not only contemplate but encourage special masters to decide petitions on the papers rather than via evidentiary hearing, where (in the exercise of their discretion) they conclude that the former

means of adjudication will properly and fairly resolve the case. Section 12(d)(2)(D); Vaccine Rule 8(d). The choice to do so has been affirmed on appeal. *See Hooker v. Sec'y of Health & Human Servs.,* No. 02-472V, 2016 WL 3456435, at *21 n.19 (Fed. Cl. Spec. Mstr. May 19, 2016) (citing numerous cases where special masters decided on the papers in lieu of hearing and that decision was upheld). I am simply not required to hold a hearing in every matter, no matter the preferences of the parties. *Hovey v. Sec'y of Health & Human Servs.,* 38 Fed. Cl. 397, 402-03 (1997) (special master acted within his discretion in denying evidentiary hearing); *Burns,* 3 F.3d at 417; *Murphy v. Sec'y of Health & Human Servs.,* No. 90-882V, 1991 WL 71500, at *2 (Ct. Cl. Spec. Mstr. Apr. 19, 1991).

ANALYSIS

After careful review of the expert reports, medical records, and the arguments of both sides, and taking into account my own experience resolving similar claims (as well as parallel decisions from other Vaccine Act cases), I conclude that Petitioner has not established preponderant evidence in favor of her claim.

A. Petitioner Has Not Shown that B.P. Had Any Mitochondrial Disease or Dysfunction.

As I previously noted in *R.V. v. Sec'y of Health & Human Servs.*, No. 08-504V, 2016 WL 3882519, at *26 (Fed. Cl. Spec. Mstr. Feb. 19, 2016), *mot. for review den'd*, 127 Fed. Cl. 136 (Fed. Cl. July 1, 2016), *appeal dismissed*, No. 16-2400 (Fed. Cir. Oct. 26, 2016), mitochondrial disease or dysfunction includes a number of disorders affecting the body's ability to metabolize energy. It can manifest with a multitude of symptoms, including autism – although autism has yet to be persuasively linked causally to the condition. *Id.* A true mitochondrial disease is distinguishable from a lesser form of dysfunction; the former usually presents with severe, clinically-recognized symptoms and is often conclusively diagnosed by genetic testing, while mitochondrial dysfunction (also called "secondary" mitochondrial disease) can be the byproduct of a different disease or merely reflect a transient problem. *R.V.,* 2016 WL 3882519, at *26; *Anderson v. Sec'y of Health & Human Servs.*, No. 02-1314V, 2016 WL 8256278, at *24 (Fed. Cl. Spec. Mstr. Nov. 1, 2016), *mot. for review den'd, slip op.,* (Fed. Cl. Apr. 20, 2016). The presence of mitochondrial dysfunction can be evaluated by consideration of the results of several lab tests, applied to different diagnostic criteria. Cohen Rep. at 14; *R.V.,* 2016 WL 3882519, at *26.

The facts of this case do not support a likely diagnosis of mitochondrial dysfunction or disease, genetically-based or otherwise. As Dr. Cohen's report summarized, the various lab tests performed on B.P. not only confirmed that he did not have a prior mitochondrial disease (as best evidenced by the negative genetic testing), but also did not confirm the existence of other

biological markers that would be expected even if B.P. suffered from some lesser/secondary form of mitochondrial dysfunction. Cohen Rep. at 13-19.

Thus, analyte testing for serum lactate, blood amino acids, and urine organic acids levels all produced results in the normal range. *See, e.g.*, Ex. 11 at 2-5. Such testing can detect the presence of an abnormal concentration of molecules, which may indicate mitochondrial dysfunction – but it did not in this case. Cohen Rep. at 14. The few results that could reasonably be characterized as abnormal, such as ketosis or an isolated blood lactate level, did not outweigh the other normal results. *See* Ex. 17 at 1; Cohen Rep. at 15-17, 20.[23] And other testing that could have revealed neurologic injury reflective of an encephalopathy (such as an EEG and MRI performed on B.P.) also produced normal results. Cohen Rep. at 15.

Similarly, there is no evidence in the record of a genetically-based mitochondrial disease. Ex. 35 at 5. B.P. underwent genetic karyotyping, chromosomal microarray, Fragile X, whole exome sequence, and mitochondrial DNA testing – and all of these tests produced normal results. Ex. 5 at 90, 113-16; Ex. 28 at 3; Ex. 30 at 1-2; Cohen Rep. at 17. Genetic tests for MECP2 and congenital disorders of glycosylation were also negative. Ex. 17 at 1.[24] And in any event, as Dr. Cohen persuasively established in his report, had B.P. in fact possessed a genetically-derived mitochondrial disease or dysfunction, the disease would most likely manifest by causing "death in the first few years of life" – something that (thankfully) did not occur in this case. *Id*. at 18.

The primary factual support Petitioner offered for the mitochondrial dysfunction diagnosis is derived from the records of Drs. Frye and Kendall, and the opinions expressed therein. But these materials provide weak support for Petitioner's claim. Both of their evaluations of B.P. were premised upon factually unsupported histories of regression following vaccination provided by his parents, rather than a treater's reasoned interpretation or evaluation of the actual medical record. Cohen Rep. at 18-19; Ex. 17 at 1-2; Ex. 25 at 1-7. Dr. Kendall in fact never even concluded that B.P. had some form of mitochondrial disease, but rather at best

[23] Such limited positive results were also not persuasive evidence of mitochondrial dysfunction for other reasons. Thus, as Dr. Cohen stated (and unrebutted by Petitioner), ketosis is common after fasting and can be explained by things like poor nutritional intake, making it too non-specific to give a positive result significant weight. Cohen Rep. at 20; Ex. 46 at 2-5; Ex. 47 at 1-7. Likewise, a single abnormal blood lactate level, within a context of other normal biochemical tests, cannot stand alone in establishing mitochondrial disease or dysfunction, since performing lactic acid determinations, particularly in children with autism, can be difficult and often results in false positives. Cohen Rep. at 15-17. Because of this, specialists experienced in diagnosing mitochondrial disease typically order concomitant amino acid testing, which is more reliable evidence than an isolated elevation in blood lactate. *Id*. at 17. Here, however, neither the blood amino acid testing nor urine organic acids testing in B.P. was suggestive of mitochondrial dysfunction or disease. *Id.*

[24] As noted above, the only genetic testing result for B.P. that could support Petitioner's theory was evidence of a single heterozygous variant on the NRXN1 gene – but this finding is not clinically significant, since evidence of *two* mutations would be required for the variants to produce mitochondrial dysfunction. *See* Ex. 20 at 1; Cohen Rep. at 17-18.

allowed that it was possible. Ex. 25 at 5. Two other treating physicians, Drs. Taravath and Koeberl, were similarly reluctant to make that diagnosis. *See* Ex. 46 at 10; Ex. 16 at 8-9. Of course, even where a treater expresses certainty that a particular diagnosis is correct, I need not accept it, but may instead weigh it in the context of the overall treatment history. *Snyder*, 88 Fed. Cl. at 746 n.67. Here, when such treater views are both equivocal and based on uncorroborated medical histories, they merit even less evidentiary weight.

The specific objective evidence that some of B.P.'s treaters used to conclude that he likely had mitochondrial dysfunction is also insufficiently reliable. For example, Dr. Frye appears to have relied on the buccal swab analysis to formulate his working diagnosis, but there are several problems with relying on such a test, as Dr. Cohen persuasively established. *See* Cohen Rep. at 16. In particular, the buccal swab analysis is only a research test, and therefore even if its results in this case provide some support for the existence of a complex I deficiency, it did not supply a recognized clinical criterion for the existence of mitochondrial dysfunction. *Id*. at 16, 20-21. Certainly, without additional corroborative testing results, it cannot be relied upon alone to establish preponderant evidence of mitochondrial dysfunction – and Petitioner offered nothing from either of her experts that would rebut Dr. Cohen's view of the overall validity of this test. Nor has Petitioner offered medical literature that would bulwark the reliability of the buccal swab analysis.

The record also does not support the conclusion that B.P. suffered from an IgG deficiency evidencing underlying mitochondrial dysfunction, as Dr. Harum proposed. Ex. 5 at 29. First, Dr. Harum's report never explained why an IgG deficiency would necessarily help establish the existence of a metabolic disorder like mitochondrial disease. But even if she had, Dr. Roberts – the Duke immunologist who evaluated B.P. – characterized B.P.'s IgG levels as only mildly low and most likely due to transient causes, such as hypogammaglobulinemia of infancy. Ex. 23 at 11. After consideration of test results, Dr. Roberts concluded that B.P. had normal immunologic function with no need for IVIG treatments intended to strengthen a deficient immune system. *See* Ex. 23 at 7-12; Cohen Rep. at 13, 19. Petitioner has suggested no reason why I should find Dr. Harum's views more persuasive than Dr. Roberts's – and after my own independent review of the record, I conclude otherwise.

There is also a lack of pre-vaccination evidence supporting Petitioner's contention that B.P. suffered from mitochondrial dysfunction. No treaters around the time of the relevant vaccinations, or before, ever so proposed, and Petitioner and her experts do not reference any other evidence suggesting that B.P. had a preexisting "subclinical" or "asymptomatic" mitochondrial dysfunction. Kinsbourne Rep. at 3, 6. Accordingly, Petitioner has failed under *Loving* prong one to establish that B.P.'s pre-vaccination condition included a genetic

susceptibility or subclinical mitochondrial dysfunction that was exacerbated by the relevant vaccinations.[25]

B. B.P. Did Not Experience an Acute Post-Vaccination Reaction, Regression, or Encephalopathy.

The record in this case does not support another important factual component of Petitioner's case: that B.P. experienced an immediate reaction, encephalopathic in nature or otherwise, after his fifteen-month-old vaccinations, characterized by a high fever and followed by an observable loss of eye contact and speech as well as certain motor abilities. *See* Ex. 35 at 4. It similarly does not suggest an immediate developmental regression as Petitioner alleges. To the contrary – the medical records show *no physical or developmental complaints at all* in the remaining seven months of 2011 following B.P.'s fifteen-month vaccinations in May.

The earliest evidence of any kind from the medical records that any caregiver had concerns about B.P.'s development are found in January 2012. *See* Ex. 3 at 19-21; Cohen Rep. at 19-20. And even at that time, there was no mention of regression. Rather, from May 2011 to the end of that year, the pediatric records document normal development without any indication of concerns of neurologic regression or abnormality. Ex. A at 21. There is a similar dearth of evidence concerning the alleged encephalopathic event purportedly incited by the vaccinations as described by Mrs. Pope. Petitioner cannot establish that such an event occurred simply based upon her uncorroborated allegations – and especially where those after-the-fact allegations are rebutted or unsupported by contemporaneous proof. Section 13(a)(1); *Cucuras*, 993 F.2d at 1528.[26]

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[25] Petitioner has also failed to establish a concurrent (albeit less-emphasized) explanation for B.P.'s regression and/or autism, as reflected in Dr. Harum's report: that B.P. had an underlying immunological dysfunction that impaired his ability to absorb the impact of his May 2011 vaccinations. Dr. Kinsbourne also proposes that B.P.'s "vulnerability to infections" was attributable to a lowered level of immunoglobulin. *See* Kinsbourne Rep. at 3. A core component of this aspect of the causation theory would be Dr. Harum's supposition that B.P.'s low IgG levels reflected immune dysregulation – but not only was her opinion rebutted more persuasively by Dr. Roberts's view (set forth in the medical records) that the low levels were transient and/or not uncommon, but by the fact that Dr. Harum's own treatment of those levels was ineffective – casting further doubt on the existence of an underlying immunological dysfunction.

[26] It is instructive to compare the facts of this case with those exceedingly rare cases in which a claimant has established an encephalopathy resulting in ASD-like symptoms (although both are also distinguishable because they involved Table claims in which causation was assumed). In one such instance, the vaccinated child developed a very high fever within 48 hours of vaccination, thereafter displaying crying, sleeplessness, and significant motor problems, all of which were documented in the medical record. *Poling v. Sec'y of Health & Human Servs.*, No. 02-1466V, 2011 WL 678559, at *1 (Fed. Cl. Spec. Mstr. Jan. 28, 2011). In another, the vaccinated child received a multi-virus vaccine and experienced a seizure on the trip home from the vaccination, followed by a week of noticeably decreased levels of consciousness and lethargy. *Wright v. Sec'y of Health & Human Servs.*, No. 12-423V, 2015 WL 6665600 (Fed. Cl. Spec. Mstr. Sept. 21, 2015). As discussed in *R.V.*, an encephalopathy of this severity would be required to prompt a drastic regression of the type Petitioner alleges. *See R.V.*, 2016 WL 3882519, at *36. In Petitioner's case, by contrast, there are no records establishing any sort of proximate temporal reaction to the vaccines that would support a finding that B.P. experienced such an encephalopathy.

The subsequent records from 2012 provide little additional aid to Petitioner in this regard. The initial evaluation and diagnosis by CDSA in July 2012 note no such history or regression, and instead describe only a history of developmental delay. *See* Ex. 18; Cohen Rep. at 12. But this is after several months passed without record evidence that the Popes or B.P.'s treaters remained concerned about B.P.'s development. The records otherwise do not establish any regression of skills in this period, as opposed to a cessation of development, and therefore (as Dr. Cohen suggests) better support the conclusion that B.P.'s development problems were consistent with the experience of children with idiopathic autism.

In order to find that Petitioner had established her burden of proof with preponderant evidence on this point, I would have to accept Petitioner's personal recitation of the facts, along with her explanation that treaters simply ignored her concerns and therefore did not record what she told them. But to do so would fly in the face of the records, as well as existing legal tenets for resolving disputes between contemporaneous medical records and after-the-fact witness statements. Controlling law gives greater weight to the former, based on the reasonable proposition that an individual would more likely than not tell a treater of an observed medical problem or concern – and that in turn the treater (in the effort to provide the best care possible) would note such concerns in the relevant record. *Cucuras*, 993 F.2d at 1528. It is too great a factual leap, when the records fail to memorialize Mrs. Pope's allegations that she informed B.P.'s pediatricians about the onset of his developmental problems, to accept her assertion that at every turn such treaters ignored her concerns, making those records untrustworthy.

C. Petitioner Has Not Established a Reliable or Persuasive Causation Theory.

Petitioner's theory – that the DTaP and PCV vaccines, separately or in concert, could precipitate an encephalopathic event in a person with some degree of underlying mitochondrial dysfunction, resulting in developmental regression and, eventually, an ASD diagnosis – lacks reliability both in a specific and more general sense.

With respect to the specific evidence offered in this case, neither of Petitioner's expert reports offers a trustworthy or persuasive opinion. Thus, as noted above, Dr. Harum's report simply repeats what is contained in the medical records, with little commentary or analysis. It does not express an opinion as to the likelihood of the diagnoses at issue in this case, or set forth a medical theory or logical sequence of cause and effect connecting any of B.P.'s vaccinations with his subsequent condition. Because Dr. Harum was a treater, the fact that she was asked to provide an expert opinion in this case gave her the opportunity to expand on why (as reflected in the contemporaneous records) she assessed B.P. with encephalopathic regression into autism, IgG deficiency, and/or mitochondrial insufficiency (*see, e.g.*, Ex. 5 at 24-40; Ex. 7 at 1-3; Ex. 8 at 1-14) – yet she completely declines the opportunity to do so. I have given consideration to

what I take to be her views based on her treater status, and as reflected in the actual records – but I do not find those views in this case merit significant weight.

I also find that Dr. Harum's treatment opinions about the nature of B.P.'s development were based on unsubstantiated assumptions. For example, in both her initial evaluation and subsequent report, Dr. Harum notes that Petitioner reported a dramatic change in B.P. after fifteen months of age (the date she mistakenly[27] assigned as the time B.P. had tubes placed in his ears) – an assertion the record flatly rejects. *Compare* Harum Rep. at 3-4 *with* Ex. 3 at 33-37 (detailing normal 16- and 17-month check-ups). It appears she largely accepted the medical history that Petitioner provided to her, without looking to see if the actual record corroborated it. She also claims that Mrs. Pope's allegations as to timing "are supported by evidence in the Wilmington Health pediatric record, [her] examination and examination by the CDSA developmental evaluation agency," and that the observations during the CDSA evaluation on July 19, 2012, "make a case for ongoing developmental regression." Harum Rep. at 4-5. But there are no such reports of regression contained in the contemporaneous WHC records or the CDSA evaluation (which discuss developmental *delay*). *See generally* Exs. 3 and 18.[28] An expert opinion based on demonstrably false factual assumptions does not gain heft simply because it comes from an expert; to the contrary, it loses persuasiveness and reliability if its factual assumptions are false. *See, e.g., Davis v. Sec'y of Health & Human Servs.*, 20 Cl. Ct. 168, 173 (1990); *Raley v. Sec'y of Health & Human Servs.*, No. 91-732V, 1998 WL 681467, at *7 (Fed. Cl. Spec. Mstr. Aug. 31, 1998) ("the conclusions of an expert are only as sound as their factual predicate").

Dr. Kinsbourne's opinion suffers from similar, facially-evident persuasiveness problems stemming from unexamined factual assumptions that underlie his conclusions. Putting aside legitimate questions surrounding his expertise to opine on the matters at issue,[29] Dr.

[27] Thus, as noted above, Dr. Harum's initial evaluation placed B.P.'s alleged regression as contemporaneous with his tympanostomy tube placement at around fifteen months of age (Ex. 5 at 38), when in fact B.P. had his ear tubes inserted in December 2010 (Ex. 3 at 49-51), when he was less than one year old.

[28] Dr. Harum's opinion herein faces credibility problems similar to those that have arisen when she has offered an opinion in other cases also alleging autism as a vaccine injury. Thus, in *Fester v. Sec'y of Health & Human Servs*. No. 10-243V, 2016 WL 1745436 (Fed. Cl. Spec. Mstr. Apr. 7, 2016), Chief Special Master Dorsey specifically decried a lack of a foundation as a reason for finding Dr. Harum's opinions merited little weight. *Fester*, 2016 WL 1745436, at *15, 22. In *Fester*, Chief Special Master Dorsey ruled on the record that the petitioners were not entitled to compensation for their claim that their child's encephalopathy and/or autism was vaccine-caused. In so doing, the chief special master noted that Dr. Harum's opinion was based on "factual inaccuracies and medical presumptions which are not supported by [the] medical records," such as (a) that the child in question experienced regression post-vaccination, and (b) that the child had some underlying condition that was exacerbated by a vaccine. *Id.* at *13-14, 24.

[29] As a pediatric neurologist, Dr. Kinsbourne has expertise in testifying about autism – but barely sufficient expertise to opine on the interplay between vaccines and underlying metabolic deficiencies sufficient (after prompting by a vaccine) to produce a neurologic injury like autism. He is also not an expert on the topic of mitochondrial disease – the foundation of Petitioner's theory.

Kinsbourne's report places too much reliance on Petitioner's allegations about B.P.'s condition instead of the actual medical records. Indeed – he disregards the contemporaneous pediatric records, which contradict Petitioner's account, in forming his opinion in this case. *See* Kinsbourne Rep. at 3. His opinion is thus premised on the demonstrably-incorrect assumption that B.P. suffered a regression in temporal proximity to his fifteen-month vaccinations, a matter he admits is critical to his opinion's viability. *Id.* ("[w]hether the DTaP and Prevnar vaccinations constitute the risk factor that transformed the disorder from a subclinical to a clinical level depends in the first instance on when the autistic regression began.").

Beyond the above, Dr. Kinsbourne's opinion is unpersuasive in providing reliable scientific grounds supporting the conclusion that B.P.'s vaccinations could – and did – cause his developmental delay. Dr. Kinsbourne clearly limits his opinion to a significant aggravation claim alleging that the DTaP and PCV vaccines exacerbated B.P.'s preexisting asymptomatic mitochondrial deficiency, resulting in his current autistic condition. In support of his general theory, Dr. Kinsbourne associates autism with mitochondrial dysfunction by claiming that "[c]hildren with autism are more likely to have mitochondrial dysfunction than typically developing children." Kinsbourne Rep. at 4.

But this assertion finds minimal scientific support, at least based on literature filed in this case. To the extent that he is relying on a single study (J. Shoffner et al., *Fever Plus Mitochondrial Disease Could Be Risk Factors for Autistic Regression*, 25(4) J. Child Neurol. 429 (Jun. 2009) (filed as Ex. 64) ("Shoffner")), or case report (J. Poling et al., *Developmental*

Dr. Kinsbourne has often testified in Vaccine Program cases on behalf of petitioners in a variety of contexts. *See, e.g., Hammitt v. Sec'y of Health & Human Servs.*, No. 07-170V, 2010 WL 3735705, at *8 (Fed. Cl. Spec. Mstr. Aug. 31, 2010) (alleging that the petitioner's DTaP vaccination caused her Dravet Syndrome), *on reconsideration*, 2011 WL 1135878 (Fed. Cl. Mar. 4, 2011), *mot. for review den'd*, 98 Fed. Cl. 719 (2011), *aff'd*, 676 F.3d 1373 (Fed. Cir. 2012). But other special masters have observed deficiencies in his capacity to opine on certain topics, due in part to his lack of recent clinical expertise:

> A significant concern regarding Dr. Kinsbourne's reliability as an expert witness is that he has not maintained a "hospital based clinical pediatric neurology practice" since 1981. . . . Dr. Kinsbourne's testimony reflected his lack of recent clinical practice. His testimony was highly generalized and lacked any grounding in practice. While Dr. Kinsbourne may keep current with medical literature, . . . his testimony amounts to little more than repeating snippets from that literature.
>
> He has no current experience or context outside of "behavioral aspects" of pediatric neurology with which to apply, question, or discuss an article's teachings. . . . Dr. Kinsbourne does not publish, research, teach, counsel, attend meetings or conferences, or have any special training in the field of genetics. . . . Nor does Dr. Kinsbourne have any "experience or training or knowledge in clinical genetics, molecular genetics, and neurogenetics." . . . The fact that for the past twenty-five years Dr. Kinsbourne has not focused his practice, research or teachings in the field of seizure disorders, and that Dr. Kinsbourne has no expertise in the field of genetics significantly limited his ability to offer reliable, persuasive, and cogent testimony in this case.

Id. at *8 (internal citations omitted).

Regression and Mitochondrial Dysfunction in a Child with Autism, 21(2) J. Child Neurol. 170-72 (2006)) (filed as Ex. 63) ("Poling") to bridge this analytical gap between vaccination and autism (see Kinsbourne Rep. at 4-7), they fail to do so.

Poling is a case report involving a single child later diagnosed with mitochondrial disease. The child had received several vaccinations, and then within 48 hours developed a high fever that became low-grade over the next several days, along with inconsolable crying, sleeplessness, and significant, noticeable motor problems that worsened over the next several days. Poling at 1. There, not only was the mitochondrial disease diagnosis supported, but the reaction to the vaccines was facially undeniable – unlike in this case.

Shoffner, while a legitimate piece of scientific literature, is also unhelpful given the present facts. That study looked at the relationship between autistic *regression* in patients with mitochondrial dysfunction and fever – not vaccination and fever and/or autism. Shoffner at 1. Indeed, as Shoffner succinctly acknowledges, "[a]utistic regression was not associated with vaccination." Shoffner at 3, 4 ("[i]n our patients with mitochondrial disease and autistic spectrum disorders, the vaccines did not appear related to the neurologic regression."). Shoffner cannot be put to work on behalf of Petitioner's theory in the way she attempts – especially when B.P. did not even experience a fever after the May 2011 vaccinations (at least based on the medical records), where there is no medical record support for the conclusion that he experienced developmental regression, and where his developmental problems in fact took months thereafter to manifest.[30]

Dr. Kinsbourne's opinion was otherwise persuasively rebutted. As Dr. Cohen aptly explained in response, "[a]lthough autism can be seen in children who also have mitochondrial disorders, the two have not been causatively linked and those children either have additional clinical features or diagnostic biochemical-genetic-histological features that extend beyond the autism diagnosis," which were not present in B.P.'s case. Cohen Rep. at 14. Petitioner has offered nothing in response. And (in contrast to both Drs. Kinsbourne and Harum) Dr. Cohen has demonstrably superior expertise in the field of mitochondrial disease. This, along with the comprehensive and detailed character of his expert report, led me to give his opinions greater weight than Dr. Kinsbourne's on these matters.[31]

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[30] Additionally, the Federal Circuit's decision in *Paluck* does not compel a finding that Dr. Kinsbourne's causation theory here is legally sufficient to meet Petitioner's burden, whether under the first *Althen* prong or fourth *Loving* prong. Besides involving far more extreme facts than herein, in *Paluck* the Federal Circuit made no findings whatsoever with respect to the reliability of the petitioners' medical theory – nor was it asked to on appeal. By contrast, there are numerous apposite cases where the reliability of the medical theory connecting autism to mitochondrial disease has been successfully challenged. *See, e.g.*, *Bast*, 2012 WL 6858040, at *25-39. Accordingly, the results in a single outlier case like *Paluck* provide no persuasive grounds for a similar determination herein.

[31] Because Mrs. Pope cannot establish that B.P. suffered from the underlying mitochondrial disorder so integral to her causation theory, coupled with the facial weaknesses of her expert reports, I need not engage in a full *Althen*

Besides such problems with the expert opinions specifically offered in this case, however, Mrs. Pope's theory had a more general credibility problem. Petitioner relies on a causation theory that has been universally rejected when raised in prior Vaccine Program cases. To date, every non-Table claim litigated since completion of the Omnibus Autism Proceeding[32] seeking compensation for autism injuries purportedly related to a vaccine has failed. *See, e.g., Hardy v. Sec'y of Health & Human Servs*., No. 08-108V, 2015 WL 7732603, at *4-5 (Fed. Cl. Spec. Mstr.

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analysis herein. *See, e.g., Lasnetski v. Sec'y of Health & Human Servs.*, 128 Fed. Cl. 242, 264 (2016) (not error for special master to forgo *Althen* analysis after determining that a petitioner had not in fact experienced the disease or illness alleged to have been vaccine-caused), *citing Hibbard*, 698 F.3d at 1365. However, Petitioner has also failed to establish the third *Althen* prong of a medically acceptable timeframe. The only evidence offered to support a proximate temporal relationship in this case is set forth in a brief paragraph in Dr. Kinsbourne's report, where he proposes, conclusorily, that B.P.'s "autistic disorder originated within a medically reasonable temporal relationship to the two vaccinations." Kinsbourne Rep. at 6. Citing Shoffner, Dr. Kinsbourne alleges that "any mitochondrial reaction to an infection or vaccination typically becomes evident by two weeks after the provocative event." *Id*. However, as explained above, Shoffner looked only at the relationship between autistic regression and *fever*, not regression after vaccination, and thus does not stand for the proposition for which it has been cited. Moreover, the medical records do not establish that B.P. suffered from a fever in connection with his fifteen-month vaccinations, that his developmental problems began not long after the vaccinations, or that he experienced regression as opposed to developmental delay.

[32] In the Omnibus Autism Proceeding ("OAP"), thousands of petitioners' claims that certain vaccines caused autism were joined for purposes of efficient resolution. A "Petitioners' Steering Committee" was formed by many attorneys who represent Vaccine Program petitioners, with about 180 attorneys participating. This group chose "test" cases to represent the entire docket in the OAP, with the understanding that the outcomes in these cases would be applied to cases with similar facts alleging similar theories.

The Petitioners' Steering Committee ultimately chose six test cases to present two different theories regarding autism causation. The first theory alleged that the measles portion of the MMR vaccine precipitated autism, or, in the alternative, that MMR plus thimerosal-containing vaccines caused autism, while the second theory alleged that the mercury contained in thimerosal-containing vaccines could affect an infant's brain, leading to autism.

The first theory was rejected in three test case decisions, all of which were subsequently affirmed. *See generally Cedillo v. Sec'y of Health & Human Servs*., No. 98-916V, 2009 WL 331968 (Fed. Cl. Spec. Mstr. Feb. 12, 2009), *mot. for review den'd*, 89 Fed. Cl. 158 (2009), *aff'd*, 617 F.3d 1328 (Fed. Cir. 2010); *Hazlehurst v. Sec'y of Health & Human Servs*., No. 03-654V, 2009 WL 332306 (Fed. Cl. Spec. Mstr. Feb. 12, 2009), *mot. for review den'd*, 88 Fed. Cl. 473 (2009), *aff'd*, 605 F.3d 1343 (Fed. Cir. 2010); *Snyder v. Sec'y of Health & Human Servs*., No. 01-162V, 2009 WL 332044 (Fed. Cl. Spec. Mstr. Feb. 12, 2009), *aff'd*, 88 Fed. Cl. 706 (2009).

The second theory was similarly rejected. *Dwyer v. Sec'y of Health & Human Servs*., No. 03-1202V, 2010 WL 892250 (Fed. Cl. Spec. Mstr. Mar. 12, 2010); *King v. Sec'y of Health & Human Servs*., No. 03-584V, 2010 WL 892296 (Fed. Cl. Spec. Mstr. Mar. 12, 2010); *Mead v. Sec'y of Health & Human Servs*., No. 03-215V, 2010 WL 892248 (Fed. Cl. Spec. Mstr. Mar. 12, 2010).

After the OAP's conclusion, a total of 11 lengthy decisions by special masters, the judges of the U.S. Court of Federal Claims, and the panels of the U.S. Court of Appeals for the Federal Circuit had unanimously rejected the petitioners' claims. These decisions found no persuasive evidence that the MMR vaccine or thimerosal-containing vaccines caused autism. The OAP proceedings concluded in 2010.

Nov. 3, 2015) (referencing eleven autism claims unsuccessfully tried, plus six that were rejected (over the petitioners' objections) without trial).[33]

The same result has occurred in those cases where – like Petitioner herein – claimants assert that a child's underlying metabolic disorder (most commonly a mitochondrial disease of some kind) was exacerbated by a vaccine, resulting in a developmental regression or autism. *See, e.g., Hardy*, 2015 WL 7732603, at *4-5 (petitioners failed to demonstrate that DTaP vaccine caused or significantly aggravated underlying mitochondrial disease resulting in ASD); *R.V.*, 2016 WL 3882519, at *42, *mot. for review den'd*, 127 Fed. Cl. 136 (2016) (factual record did not support contention that child suffered from a mitochondrial disease, or that the vaccine at issue had a causal connection to the development of ASD); *Miller v. Sec'y of Health & Human Servs.*, No. 02-235V, 2015 WL 5456093 (Fed. Cl. Spec. Mstr. Aug. 18, 2015) (petitioners failed to demonstrate that several childhood vaccines caused encephalopathy or aggravated underlying mitochondrial disease/dysfunction); *Lehner v. Sec'y of Health & Human Servs.*, No. 08-554V, 2015 WL 5443461 (Fed. Cl. Spec. Mstr. July 22, 2015) (petitioners failed to demonstrate that flu vaccine resulted in autoimmune encephalitis). The theory as presented in this case was no more compelling than the different iterations offered in the aforementioned cases.

Perhaps aware of the steep odds of prevailing, other petitioners have attempted to recast their claim that a vaccine caused an autism injury as a claim that the vaccine precipitated some form of encephalopathy (more often than not autoimmune in nature) that *later* produced developmental problems due to the resulting neurologic injury. *See, e.g., Cunningham v. Sec'y of Health & Human Servs.*, No. 13-483V, 2016 WL 4529530 (Fed. Cl. Spec. Mstr. Aug. 1, 2016), *mot. for review den'd*, slip op. (Fed. Cl. Jan. 25, 2017). But such efforts have been correctly understood as seeking to evade the weight of negative precedent involving autism claims – as here. *Cunningham*, *slip op.* at *7-8 ("[r]egardless of petitioner's attempt to differentiate this case from other autism cases by creating this second step, the Special Master rightfully classified this case as an autism case").

D. ***Althen* Analysis.**

Give the above, it is evident that Petitioner has not met her burden under the analysis set forth in *Althen* for proving a causation-in-fact claim.

[33] In a single instance, petitioners (the parents of a vaccinated child) successfully established a Table injury – an encephalopathy – after vaccination that resulted in an autistic-like developmental regression. *See, e.g., Wright*, 2015 WL 6665600. In *Wright*, the petitioners met the Table criteria for an "acute encephalopathy" following vaccination by establishing by preponderant evidence that the vaccinated child experienced a seizure followed by loss of consciousness shortly after receipt of a pertussis-containing vaccine; the severe reaction lasted for more than 24 hours, with resulting demonstrable significant changes in behavior. But the special master responsible for that decision (former Chief Special Master Vowell) explicitly noted in her decision that the petitioners would not have been able to establish entitlement under their non-Table claim, because their expert presented a causation opinion that she found "absurd and biologically impossible." *Wright*, 2015 WL 6665600, at *2.

Prong One

As already noted, Mrs. Pope has failed to offer a reliable medical or scientific theory explaining how the DTaP or PCV vaccines could aggravate an underlying mitochondrial disease or lesser disorder, causing regression or other developmental injuries. Her experts were unpersuasive and unable to advance a reliable medical theory to support her claim, while Respondent's expert credibly rebutted the concept that an underlying mitochondrial disorder could be so affected by the relevant vaccines to initiate a process manifesting eventually as an ASD. Petitioner's general theory is also barely distinguishable from those that have been repeatedly advanced but rejected in the Program.

Prong Two

Petitioner's obligation under the second *Althen* prong was to demonstrate a logical sequence of cause and effect connecting the particular facts of her case to her medical theory. *See, e.g., Sturdivant v. Sec'y of Health & Human Servs.*, No. 07-788V, 2016 WL 552529, at *18 (Fed. Cl. Spec. Mstr. Jan. 21, 2016) (discussing that prong two requires a fact-based inquiry into whether the vaccine in question *did* cause the particular injury). But her theory depended on acceptance of her allegation that B.P. suffered from a mitochondrial disease or dysfunction – a conclusion the record does not support. Treater opinions that seemed to bulwark the theory proved unreliable, as they were based on unsupported factual histories recounted by B.P.'s parents, rather than independent review of the medical records. In addition, the medical record was bereft of reliable evidence that B.P. experienced an immediate reaction, encephalopathy, or regression following his fifteen-month-old vaccinations, despite the after-the-fact assertions of Mrs. Pope to the contrary.

Prong Three

Even if I had accepted Mrs. Pope's showing in support of her theory, B.P.'s injuries have not been shown to have occurred within a medically appropriate timeframe. Dr. Kinsbourne proposed that mitochondrial reactions to vaccinations become evident within two weeks after the triggering event. Kinsbourne Rep. at 6. Yet there were *no* contemporaneous references in the medical records supporting Petitioner's allegation that B.P. began exhibiting any different behavior or reaction to the vaccinations at issue within two weeks. In fact, there are no developmental concerns noted until January 2012, eight months following vaccination. This is simply too far removed from the vaccination to suggest a causal relationship, and Petitioner has provided no convincing evidence otherwise.

E. <u>This Case was Properly Resolved without a Hearing.</u>

In ruling on the record, I am declining Petitioner's request that I conduct a hearing. The choice of how best to resolve this case is a matter that lies generally within my discretion, but given Petitioner's protestations I shall explain my reasoning.

A hearing provides a petitioner with the opportunity to put on live testimony, which aids the special master most in cases where witness credibility is at issue or where there is a need to pose questions to a witness in order to obtain information not contained in, or not self-evident from, the existing filings. *See, e.g.*, *Hooker*, 2016 WL 3456435, at *21 (discussing a special master's discretion in holding a hearing and the factors that weighed against holding a hearing in the matter); *Murphy*, 1991 WL 71500, at *2 (no justification for a hearing where the claim is fully developed in the written records and the special master does not need to observe the fact witnesses for the purpose of assessing credibility). It may also permit a claimant to expand upon or illuminate points already set forth in paper filings, or respond to unanticipated questions raised in the matter – but again, only where necessary to reach a decision.

Prior decisions have recognized that a special master's discretion in deciding whether to conduct an evidentiary hearing "is tempered by Vaccine Rule 3(b)," or the duty to "afford[] each party a full and fair opportunity to present its case." *Hovey*, 38 Fed. Cl. at 400-01 (citing Rule 3(b)). But that rule also includes the obligation of creation of a record "sufficient to allow review of the special master's decision." *Id*. Thus, the fact that a claim is legitimately disputed, such that the special master must exercise his intellectual faculties in order to decide a matter, is not itself grounds for a trial (for if it were, trials would be required in every disputed case). Special masters are expressly empowered to resolve fact disputes *without* a hearing.[34]

In this case, live witness testimony was not required in order for me to reach a reasoned decision. The record itself was expansive and contained sufficient evidence upon which to base this decision. The flaws in Petitioner's theory and factual arguments were self-evident from review of the medical records and the two expert reports submitted, both of which relied heavily

[34] I therefore do not find persuasive Petitioner's argument that Respondent's motion is akin to one for summary judgment that cannot be granted because "disputed issues of material fact" have been raised. Opp. at 16. Petitioner has unquestionably contested certain facts, such as whether B.P. experienced regression, or some kind of severe physiologic reaction, after the May 2011 vaccinations. But in inviting the parties to brief the case on the papers, I was signaling my preliminary assessment that (given the facts at issue, as well as the nature of the causation theory) Petitioner was *not likely to succeed in this case*. That determination in turn was based upon two conclusions. First, the factual disputes were not sufficiently *material* to warrant hearing (since materiality of disputed fact issues bears heavily on when summary judgment should be granted (*see, e.g., Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986) ("only disputes over facts that might affect the outcome of the suit under the governing law will properly preclude the entry of summary judgment")). Second, Petitioner did not *reasonably* contest certain facts (*i.e.,* by gainsaying the medical records, which provided no corroboration for Mrs. Pope's assertions about what she observed was occurring to B.P. at certain points in time). It is not enough to invoke summary judgment jurisprudential considerations as a basis for holding a hearing by asserting "I object," if that objection lacks evidentiary foundation.

on witness statements that were uncorroborated by, or contrary to, the contemporaneous medical record. And, as noted above, Petitioner's experts offer opinions that are scientifically unreliable and unpersuasive, while also consistent with opinions repeatedly rejected in the Program. Such deficiencies did not require oral testimony to be understood for purposes of deciding the case. On the contrary: the congruence of the theory espoused herein with numerous, previously-rejected variations on the same theme counseled against expending the time and effort necessary for a hearing.[35]

I similarly did not need to hear directly from Petitioner or her family members about the precise timing of the onset of B.P.'s reactions or alleged regression. There are many cases where witness testimony about the nature of a symptom or its onset is critical to determining a fact issue. *See, e.g.*, *Rich v. Sec'y of Health & Human Servs.*, No. 12-742V, 2015 WL 5882324 (Fed. Cl. Spec. Mstr. Sept. 16, 2016) (fact hearing required witness testimony to determine onset of petitioner's ADEM symptoms); *Reddy v. Sec'y of Health & Human Servs*., No. 13-208V, 2015 WL 5578610 (Fed. Cl. Spec. Mstr. Aug. 26, 2015) (determining onset of symptoms through witness testimony at fact hearing to resolve whether claim was timely filed); *Bray v. Sec'y of Health & Human Servs.*, No. 10-207V, 2014 WL 5025173 (Fed. Cl. Spec. Mstr. Sept. 16, 2014) (requiring witness testimony to determine if petitioner received the flu vaccine). In such instances, it may be necessary to evaluate the witness's demeanor live in order to determine how much weight to give a factual allegation.

But here, I can dispense with live testimony, which was uncorroborated by the existing medical record. The record overwhelmingly does not support the conclusion that B.P.'s developmental problems began any time before late 2011. Mrs. Pope cannot prevail in a Vaccine Act claim simply based upon her own allegations. Where, in a case like this, the petitioner's onset allegations that a child had begun experiencing developmental decline or delay – conditions that a parent would more likely than not share with a treater – find no support in the record, I need not hear from the parent directly to find that the testimony (however heartfelt or in good faith) is less trustworthy than the contemporaneous written evidence.

I also did not require hearing from the experts directly. Both of Petitioner's experts were facially less qualified to testify on the matters in dispute than Dr. Cohen, giving me greater reason to weigh his opinions over theirs. Moreover, the deficiencies in Petitioner's experts' opinions were self-evident simply from reading them. Expert reports are intended to provide a written statement of the expert's actual opinion – not a tease of positions or views the expert may provide at hearing, thereby leaving their true opinions a surprise that will only be revealed at

[35] The decision not to hold a hearing because the claim reflected a frequently-litigated theory is not something that would only ever negatively impact a petitioner. The opposite circumstances – where a petitioner asserted a claim that has repeatedly *succeeded* in the past (for example, the allegation that the flu vaccine can cause Guillain-Barré syndrome) – would motivate me to act in the same manner, and propose to Respondent that either the case be settled or that it be resolved on the papers.

trial. I knew enough about the problems with Petitioner's experts based on the existing record to rule on this matter without hearing from them live.

At bottom, the most significant issue in deciding whether to hold a hearing is determining if the refusal to do so will deprive the claimant of the fair opportunity to prosecute her case. Petitioner here has received such an opportunity. Her chances of winning would not have increased merely because her claim was litigated in court. Indeed, as the procedural history indicates, she was given ample extensions of time to obtain Drs. Harum's and Kinsbourne's reports, and to marshal the arguments she made in opposing Respondent's motion on the record. In addition, she and her counsel are on reasonable notice of the difficulties they would face in attempting to prove an autism injury in the Vaccine Program, in light of the many negative decisions cited above that are directly relevant to her claim given the similarities of their facts as well as the causation theories attempted. Regardless of Petitioner's hopes, a hearing would not have changed the outcome, but would have unnecessarily postponed the date by which the matter could be fully resolved. Such circumstances ultimately counseled in favor of resolving the matter on the papers.

CONCLUSION

The record does not support Mrs. Pope's contention that the vaccines B.P. received could, or did, cause his developmental regression or autism, nor has she established it more likely than not that he suffered from some form of underlying mitochondrial dysfunction. Petitioner has not established entitlement to a damages award, and therefore I must **DISMISS** her claim.

In the absence of a timely-filed motion for review (see Appendix B to the Rules of the Court), the Clerk shall enter judgment in accordance with this decision.[36]

IT IS SO ORDERED.

/s/ Brian H. Corcoran
Brian H. Corcoran
Special Master

[36] Pursuant to Vaccine Rule 11(a), the parties may expedite entry of judgment by filing a joint notice renouncing their right to seek review.